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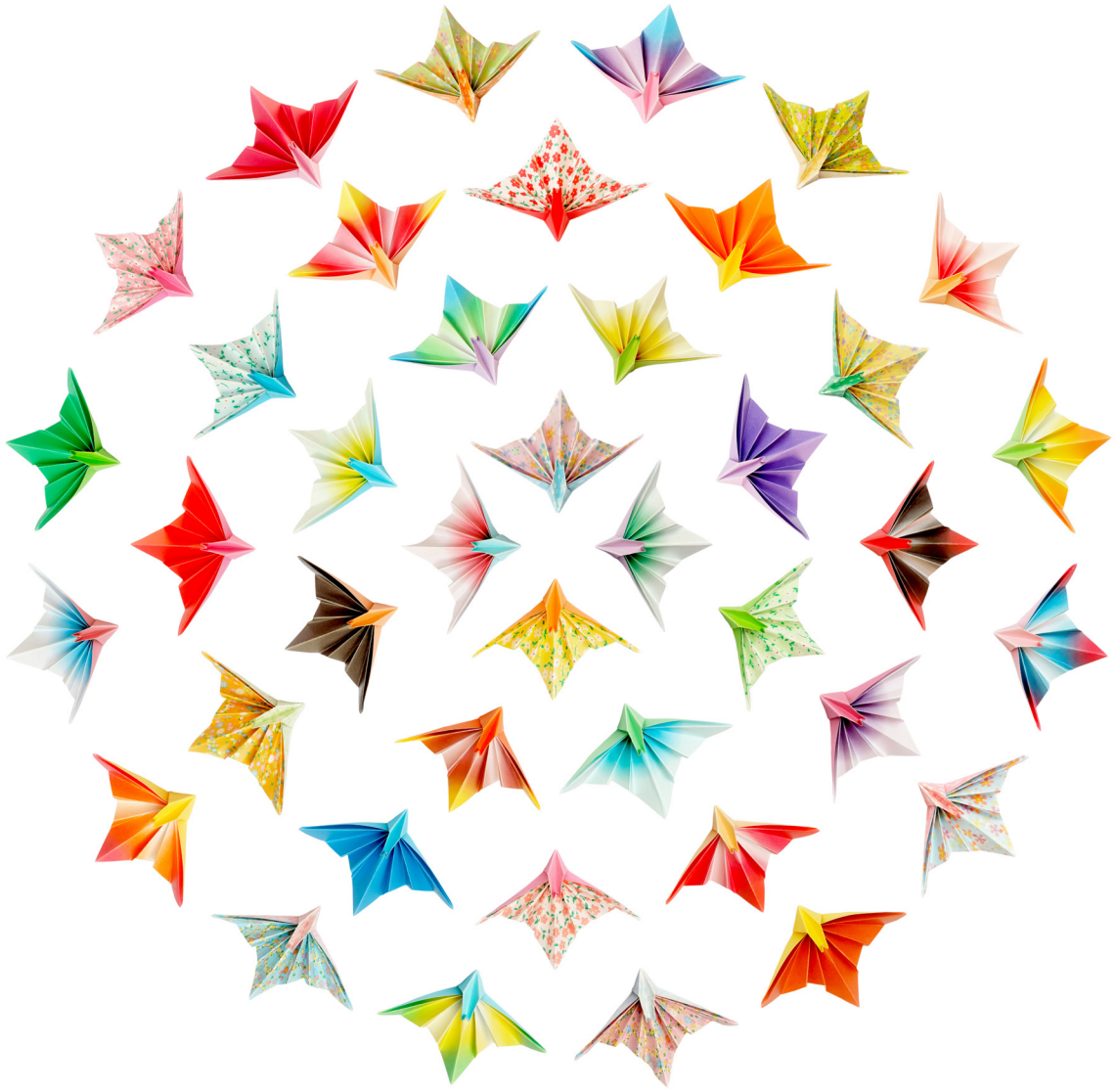
AHWP
Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

APACMed ASIA PACIFIC MEDICAL TECHNOLOGY ASSOCIATION



Competency Framework for Medical Technology Regulators

Executive Summary

Medical technology regulatory systems aim to protect and promote public health and safety while supporting innovation and access. Public trust and confidence in these systems depend on the safety and performance of medical devices throughout their life cycle.

Regulators determine the extent and complexity of regulatory oversight across each stage of the medical device life cycle. A clear and coordinated system of regulatory controls, together with manufacturers' robust quality systems, ensure that medical devices are safe, and perform as intended. The implementation of harmonized regulatory controls across jurisdictions enables cross-border leveraging of regulatory resources and reduce the burden on this highly regulated sector. More importantly, it ultimately ensures a better access to lifesaving medical products for patients.

Across Asia Pacific, markets are facing multiple challenges including fragmented regulatory systems, complex market access issues, and a shortage of regulatory professionals in both the private and public sectors. Over the last decades, international organizations, government agencies, NGOs, academia, associations, and industry have come together in an effort to build a sustainable talent pipeline of regulatory professionals across both sectors. However, the efficiency and effectiveness of these efforts have been questioned. Indeed, trainings have been deemed to be, at times, too infrequent or inconsistent. Hence, multi-stakeholder training initiatives, better-coordinated training resources, as well as the standardization of regulatory curricula are much needed.

To develop a holistic and effective training curriculum for regulatory professionals, it is critical to identify the set of common competencies essential to optimal work performance. In January 2018, the Asia Pacific Medical Technology Association (APACMed), in collaboration with Deloitte, published a white paper *"Competency Framework for Asia Pacific MedTech Regulatory Professionals"* [1], which focused on regulatory professionals in the industry.

In 2018, to expand this initiative from industry professionals to regulators, APACMed and Deloitte partnered with the regional regulatory harmonization entity, the Asian Harmonization Working Party (AHWP), to identify the Competency Framework for medical technology regulators.

This project was built on primary research and secondary research, where the latter leveraged the valuable work of the World Health Organization (WHO), the Global Harmonization Task Force (GHTF), the Asian Harmonization Working Party (AHWP), etc.

For the primary research, the project team jointly conducted surveys among both regulatory authorities and companies within the Medical Technology (MedTech) sector (including medical devices, in vitro diagnostics, and digital health, etc.) in July and August 2018. These surveys were designed to identify the competencies (knowledge, skills, and behaviours) necessary to bolster the performance capabilities of MedTech regulators. The comparative analysis of findings from the two surveys demonstrated significantly high level of consensus **(80% correlation)** between regulators and industry with regards to critical competencies necessary for MedTech regulators.

This white paper establishes 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.** While the first two dimensions (Foundational Competencies and General Technical Competencies) are the basic essential competencies regarded as universal for regulators in different economies, the third dimension (Functional Technical Competencies) represents additional core competencies split into six (6) modules, selected in accordance with different needs and stages of development of regulatory authorities in different economies.

Under each dimension, competencies were further divided into **Primary Focus, Secondary Focus, and Tertiary Focus,** based on the level of importance as rated in the regulator's self-assessment. The three different levels of importance for competencies are instrumental for economies to prioritize their training resources and thus are more critical for economies with limited resources. Training initiatives should be designed and implemented in a phased approach, starting from competencies labelled as the Primary Focus, followed by Secondary focus, and finally Tertiary Focus resources permitting.

This framework is designed to serve as a tool for developing prioritized training curricula for MedTech regulators. It is intended to be used by MedTech regulators and their training partners such as international organizations, donors, academia, associations, subject matter experts, etc. It should be noted that both the competency framework and curriculum framework initiatives should involve multiple stakeholders as mentioned above, who can play a pivotal role across every stage of the process, from the competency framework to gap assessment, from curriculum framework to training delivery as well as evaluation.

[1] Competency Framework for Asia Pacific MedTech Regulatory Professionals
http://www.apacmed.org/content/uploads/2018/03/Deloitte-APACMed-Competency-Framework-for-APAC-MedTech-RA-Professionals.pdf

Chapter 1
Introduction

Over the last decade, a wide range of stakeholders have been involved in the design, development, and delivery of training for MedTech Regulators. These include the World Health Organization (WHO), the Asia-Pacific Economic Cooperation Regulatory Harmonization Steering Committee (APEC-RHSC), the Asian Harmonization Working Party (AHWP), various professional and trade associations, academia, and industry, etc.

The demand for training on the part of MedTech regulators across the region has grown exponentially, as a result of rapid scientific and technological advancement, as well as an ever-evolving regulatory landscape.

However, the efficiency and effectiveness of existing training efforts have come under scrutiny. Multiple stakeholders have called on a better coordination of training resources, a common framework with harmonized competencies essential for them to properly perform at work, as well as holistic and prioritized training curricula based on gap assessment and resources available.

In January 2018, the Asia Pacific Medical Technology Association (APACMed) jointly with Deloitte published a white paper on *"Competency Framework for Asia Pacific MedTech Regulatory Professionals"*, which focused on regulatory professionals in the industry.

To expand this initiative from industry to regulators, in the past year, the AHWP, APACMed, and Deloitte Consulting jointly initiated a study across all AHWP member economies to develop a harmonized competency framework for MedTech regulators.

Competency framework[2] is a model that broadly describes performance excellence within an organization, including a number of competencies that are applied to multiple occupational roles within the organization. This competency framework can be leveraged to build a structured training curriculum for these regulatory agencies by themselves or together with other stakeholders.

Regulatory professionals, in both private and public sectors, should be equipped with a broad range of knowledge and skills in the fields of science, clinical practice, law and regulations, regulatory principles, statistics, communication, management, etc. Despite the variations in local legal frameworks and market segments across different economies, some of these capabilities are universal and applicable to all MedTech regulators.

These competencies are considered as basic essential competencies and are categorized as **Foundational Competencies** (both technical and administrative staff) or **General Technical Competencies** (only technical staff). However, the results of regulator's self-assessment showed that the scope of regulatory activities throughout the product lifecycles varied greatly among AHWP member economies.

Therefore, a separate **Functional Technical Competencies** dimension, which includes additional core competencies are arranged in a modular structure and can be selected according to specific needs. There are 6 modules within this dimension; while some economies have regulatory practices in all 6 functions, others might have less, depending on local regulatory requirements.

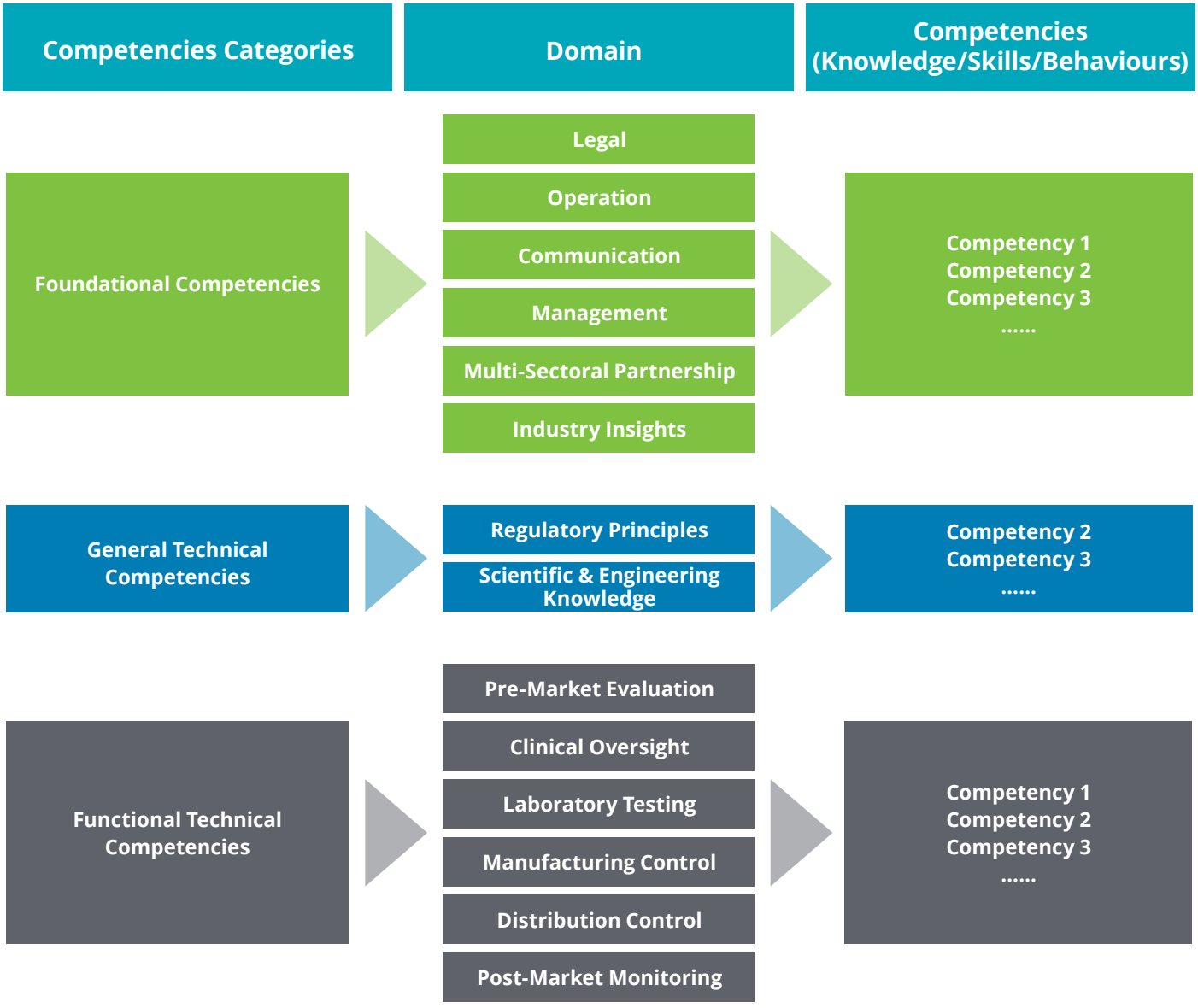
A total of ninety-seven (97) competencies were divided into three competency categories or dimensions, where thirty-eight (38) competencies were categorised as Foundational Competencies, twenty (20) as General Technical Competencies, and thirty-nine (39) as Functional Technical Competencies.

[2] The Competency Framework
https://www.iaea.org/sites/default/files/18/03/competency-framework.pdf

- **Foundational Competencies (38)** – applicable to all staff within the regulatory agency including management, technical, and administrative employees; knowledge and skills captured here were divided into six (6) domains or themes, including Legal, Operation, Communication, Management, Multisector Partnership, and Industry Insights.
- **General Technical Competencies (20)** – applicable to all technical staff in MedTech regulatory functions. These competencies were divided into two (2) domains, including the general Regulatory Principles and Scientific & Engineering Knowledge;
- **Functional Technical Competencies (39)** – applicable only to technical staff in a specific function across the product life cycle. There are in total six (6) domains or modules in accordance with 6 functions, including Pre-market evaluation, Clinical Oversight, Laboratory Testing, Manufacturing Control, Distribution Control, and Post-Market Monitoring). These competencies cover skills and detailed know-how of activities and regulatory principles specific to MedTech product lifecycle phases indicated above.

Each of these **"competencies"** are defined **as knowledge, skills, and behaviors** that are essential to fulfil role requirements across specific **"domains".** The structure of the competency framework for MedTech regulators are illustrated in Figure 1.

Figure 1. Structure of the Competency Framework for MedTech Regulators.



Chapter 2
Approach Used to Develop the Competency Framework

This white paper draws on insights from primary and secondary research to validate an initial hypothesis around critical competencies expected of Medical Technology regulators in AHWP member economies.

Findings from secondary research helped identify key activities and competencies essential for regulatory oversight in the context of the medical device lifecycle. This work builds on a robust, international evidence base including:

- the Regulatory Model[3] based on five economies of Global Harmonization Task Force (GHTF);
- the Asian Harmonisation Working Party (AHWP) Playbook for Implementation of Medical Device Regulatory Frameworks focusing on regulatory controls on importers and distributors[4];
- the World Health Organisation (WHO) Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices[5], which provides a segmentation of regulatory activities at basic level and expanded level.

This project also references capacity building projects at both international and country level, to articulate our competency framework hypothesis. These include:

- the WHO global benchmarking tool[6];
- the Medical device regulatory competency program in Malaysia.

The primary research was designed to gather regulatory authorities' self-assessments and compare them with MedTech companies' expectations of regulator knowledge and capabilities. Two surveys were conducted in July and August 2018 respectively. The first survey, carried out by AHWP, targeted MedTech regulators of AHWP member economies. Its aim was twofold:

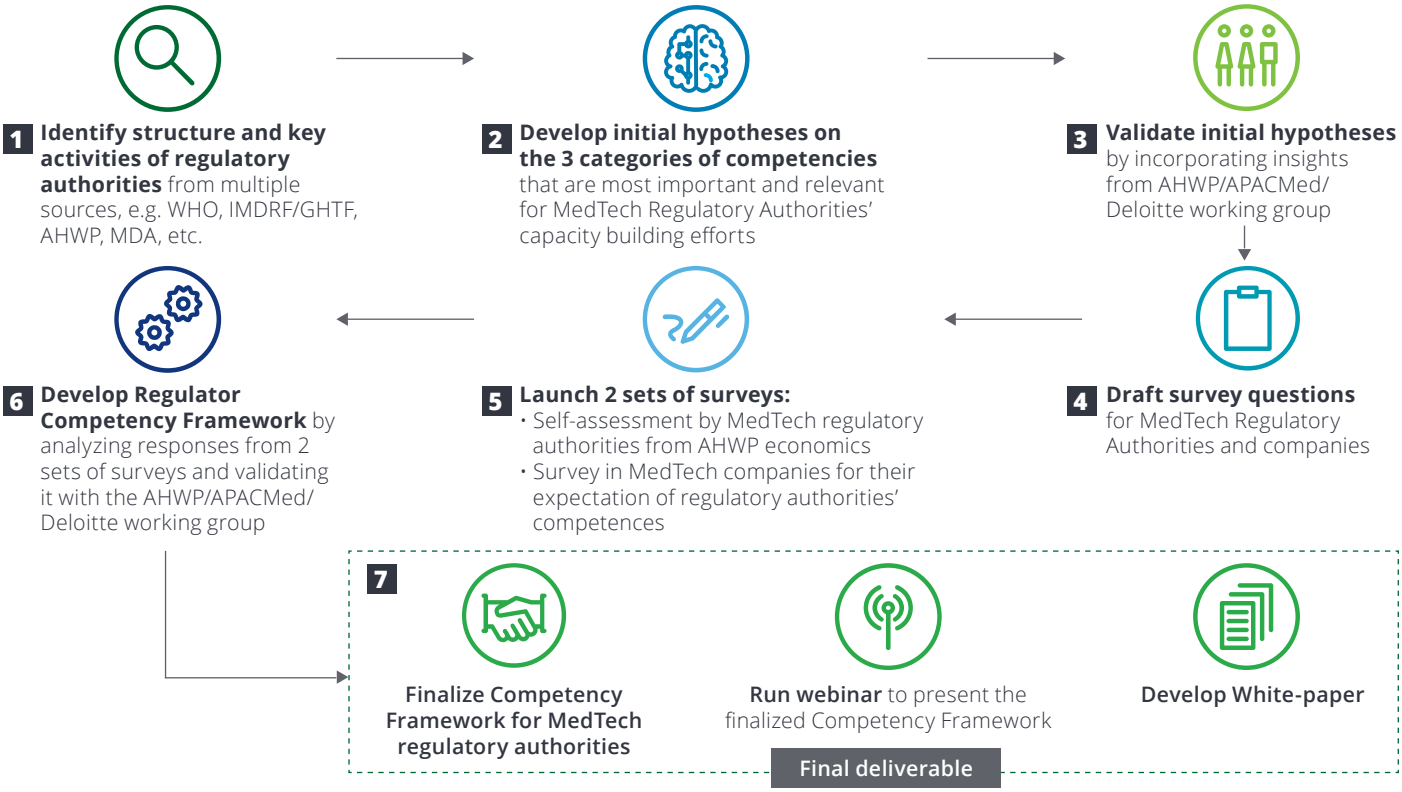
- identify the scope of regulatory activities in AHWP member economies;
- identify basic core competencies universal to regulators in different economies as well as additional essential competencies (with multiple modules which can be selected according to the specific needs of regulators in different economies).

The second survey, jointly conducted by AHWP and APACMed, targeted MedTech companies, and aimed to assess:

- their current levels of satisfaction with the overall levels of knowledge and service of MedTech Regulators;
- their expectations of regulators' competencies and skill set.

The team analyzed the data and ran a correlation test between the two surveys. These findings were then validated with key stakeholders and used to build the competency framework outlined in this white paper. Please refer to Figure 2 for more details about the approach used to develop this competency framework.

Figure 2. Competency Framework Development Approach.



[3] The GHTF Regulatory Model (2011). http://www.imdrf.org/docs/ghtf/final/steering-committee/technical-docs/ghtf-sc-n1r13-2011-ad-hoc-regulatory-model-110413.pdf

[4] AHWP Playbook for Implementation of Medical Device Regulatory Frameworks (2014). http://www.ahwp.info/sites/default/files/ahwp-files/4_Technical_Committee/AHWP%20Playbook%20for%20Implementation%20of%20MD%20Reg%20Framework.pdf

[5] WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices (2017). http://apps.who.int/medicinedocs/documents/s23213en/s23213en.pdf

[6] WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems. https://www.who.int/medicines/regulation/benchmarking_tool/en/

Chapter 3
Survey Findings of Medical Technology Regulator's Competency Framework

The MedTech industry's perceived level of satisfaction with the customer service provided by regulatory authorities varied greatly among different economies. But their levels of satisfaction were highly correlated (70%) with their ratings of clarity of regulations in these economies. MedTech industry executives working in economies where they have better clarity on regulations are thus generally more satisfied with the services provided by MedTech regulators, please refer to Figure 3 for more details.

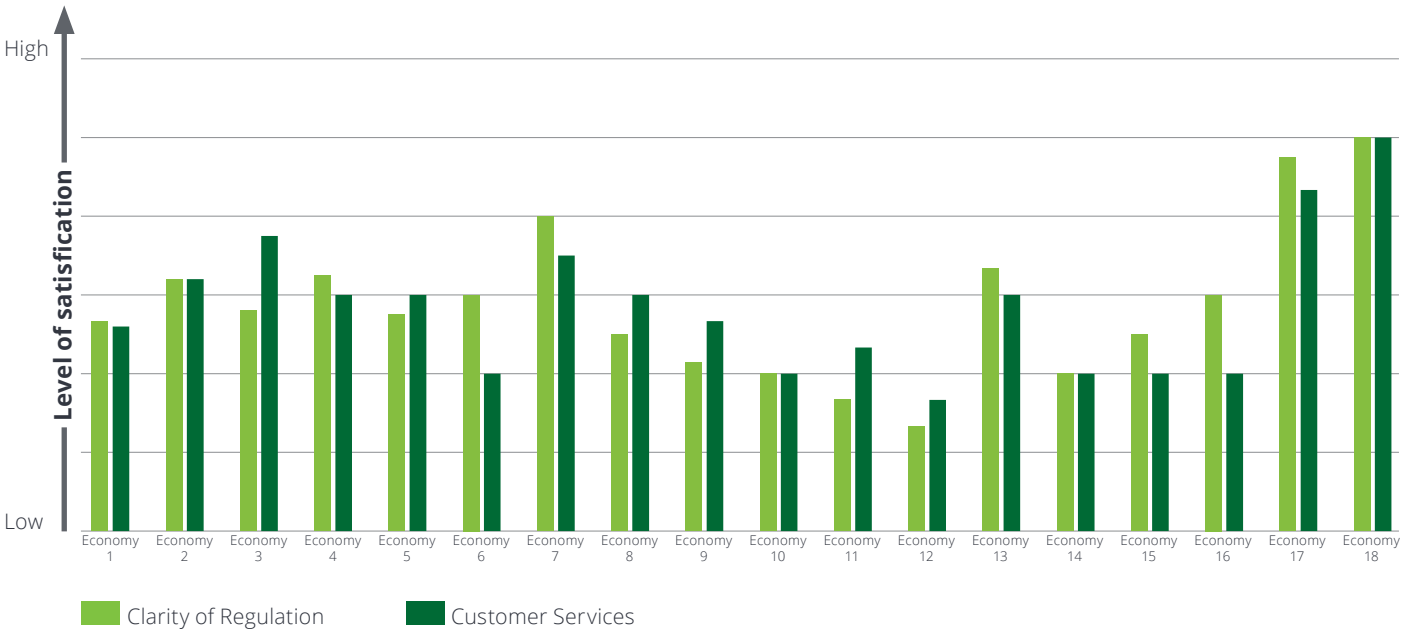
As anticipated, the MedTech industry survey revealed a great variation in levels of regulation clarity and levels of customer satisfaction, thus validating our belief in the urgent need for a more systematic and efficient approach for capacity building among MedTech regulators, based on a harmonised model and best practice sharing among different economies.

MedTech industry executives also rated the critical level for each of the ninety-seven competencies deemed to be essential for MedTech regulators to perform their role optimally. As part of the validation process, these industry ratings were then compared with the findings from the MedTech regulators' self-assessment. The comparative analysis of these two data sets indicates **a high correlation (80%),** meaning there is a significantly high level of consensus between regulators and industry with regards to critical competencies necessary for MedTech regulators.

Hence, we trust this high-level competency framework will prove to be a pertinent tool for conducting the need assessments of different stakeholders, and a solid building block for the design and development of prioritised training curricula for MedTech regulators.

MedTech regulators from thirteen (13) AHWP economies responded to the survey, including Chile, Chinese Taipei, Hong Kong SAR of China, Indonesia, Kingdom of Saudi Arabia, Malaysia, People's Republic of China, Philippines, Republic of Korea, Sultanate of Oman, Tanzania, Thailand, and Vietnam. With participating economies spread out across Asia, Middle East, South America, and Africa, findings unveiled by the regulators' self-assessment are deemed to be relevant and applicable to quite a broad range of economies across the globe.

Figure 3. MedTech Company responses on "Level of satisfaction with Customer Service" and "Clarity of Regulation" of AHWP Economies.



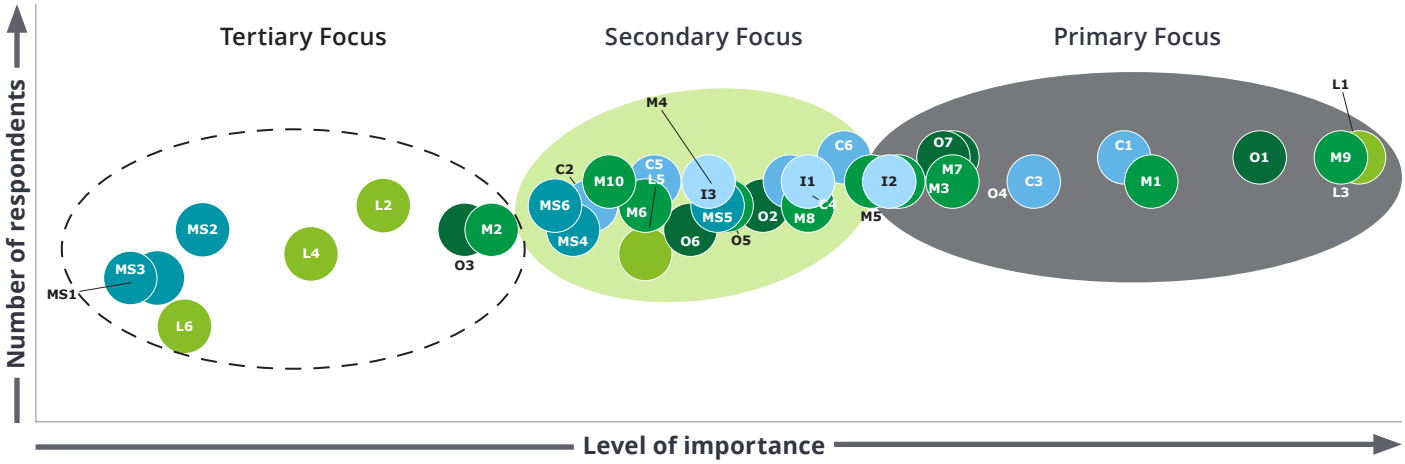
[2] Individuals primarily from commercials, supply chain and medical affair functions

As mentioned in Chapter 1, a total of ninety-seven (97) competencies were grouped into three dimensions or categories: thirty-eight (38) **Foundational Competencies** (applicable to all staff), twenty (20) **General Technical Competencies** (applicable to all technical staff in MedTech regulatory functions), and thirty-nine (39) **Functional Technical Competencies** (applicable to staff in specific regulatory functions across the product lifecycle).

The survey respondents were asked to rate the importance of each of these competencies from one (1) to five (5), with five (5) being the most critical. Within each dimension, based on the complied and averaged scores, competencies were further divided into **Primary focus** (highlighted in dark grey) (with score greater than 4.4/5), **Secondary focus** (highlighted in light green boxes) (with score between 4.1/5 to 4.4/5) and **Tertiary focus** (highlighted in white boxes) (with score less than equal to 4.1/5) for easy reference in prioritizing competencies for training purposes.

Please see the detailed mapping of Primary focus, Secondary Focus and Tertiary Focus for **Foundational Competencies** in Figure 4, that of **General Technical Competencies** in Figure 5, and that of **Functional Technical Competencies** in Figure 7.

Figure 4. Prioritization of Foundational Competencies.



Legal (L)	Operation (O)	Communication (C)	Management (M)	Multisector Partnership (MS)	Industry Insights (I)
1 Legal Documents (local)	1 Code of Conduct	1 Effective Communication	1 Quality Mgmt. System	1 Foreign Languages & Culture	1 Local Industry Landscape
2 Legal documents (international)	2 Critical Thinking & Problem Solving	2 Public Speaking	2 Project Mgmt.	2 Diplomatic and Foreign Affairs Policy	2 Emerging Technologies and Products
3 Technical Documents (local)	3 Budget Planning & Management	3 Interpersonal Skills	3 Risk Mgmt.	3 Healthcare Ecosystem	3 International Industry Landscape
4 Technical Documents (international)	4 Documentation & Filing	4 Negotiation	4 Crisis Mgmt.	4 Stakeholder Engagement	
5 Legislative Process	5 Customer Service	5 Information Dissemination & Media Strategy	5 People Mgmt.	5 International Initiatives and Networks	
6 Legal Writing	6 IT Skills	6 Public Education	6 Mentoring & Coaching	6 Public Health	
	7 Technical Report Writing		7 Training		
			8 Leadership		
			9 Good Regulatory Practice		
			10 Policy Analysis		

Among the thirty-eight (38) **Foundational competencies,** there are 6 **Domains,** including **Legal (L), Operation (O), Communication (C), Management (M), Multisector Partnership (MS), and Industry Insights (I).** The code of each competency has two components: the abbreviation of the above-mentioned Domain plus the sequence number.

Interpreting the data in Figure 4:

- Competences highlighted in **dark grey** in the **upper right quadrant** of the chart are rated as most critical (averaged score over 4.4/5), or **Primary Focus.**
- Those highlighted in green at the centre of the chart, are rated as medium critical (averaged score between 4.1/5 and 4.4/5), or Secondary Focus.
- Those highlighted in white in the lower left quadrant are rated as less important (averaged score below 4.1/5), or Tertiary Focus.

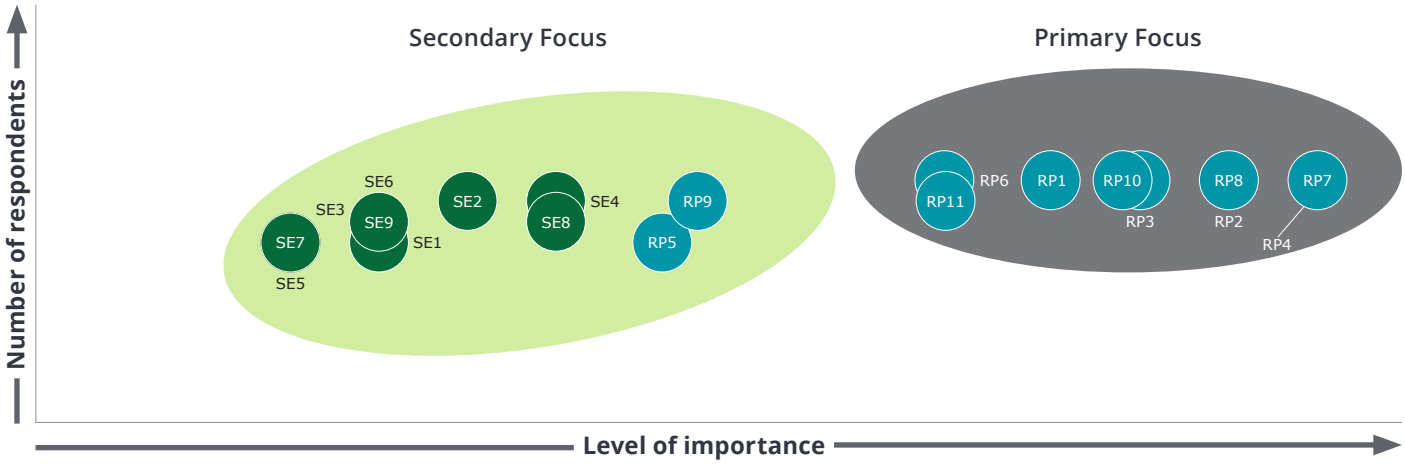
For ease of interpretation, these competencies are also illustrated in the table below the chart, and grouped by **Domains** (columns), and by **Level of importance** (boxes) , following the same colour code.

Twelve (12) out of the thirty-eight (38) Foundational Competencies are rated as Tier-1 or Primary Focus for training, and are widely spread across 5 different domains except for the domain of Multisector Partnership (MS).

Domain Deep Dive:

- **Legal (L) domain:** most regulators agree that knowledge of local laws, regulation, as well as local technical documents and standards are more important than regulations in other countries.
- **Operation (O) domain:** regulators are more likely to invest in trainings on codes of conduct, technical report writing, documentation, as opposed to IT or customer services skills.
- **Communication (C) domain:** interpersonal skills and general commutations skills are rated as more important than media strategy and public education.
- **Management (M) domain:** most regulators consider quality management, risk management, training skills and Good Regulatory Practice (GRP) to be the most important competencies, while project management knowledge is rated as less important than the rest of them.
- **Multisector Partnership (MS) domain:** none of the competencies in this domain are rated as critical, and international initiatives are only rated as medium critical, which is not consistent with findings from other projects.
- **Industry Insights (I) domain:** regulators agree it is very important to enhance their knowledge of emerging technologies and innovative products.

Figure 5. Prioritization of General Technical Competencies.



Scientific & Eng. Principles (SE)	
1	Human Anatomy and Physiology
2	Biological Science
3	Biochemistry
4	Biomaterials
5	Nanomaterials
6	Biomechanics
7	Bioelectronics
8	Radiation and Nuclear Medicine
9	Digital Technology (mobile health, telemedicine, AI, etc.)

Regulatory Principles (RP)	
1	Differences - Pharmaceuticals, General MDs & IVDs
2	Combination and Borderline Products
3	Risk Classification
4	Essential Principles of Safety & Performance
5	Device Nomenclature Systems (GMDN/UMDNS)
6	Device Labelling & Unique Device Identifier (UDI)
7	Conformity Assessment Concepts and Principles
8	Post-marketing Surveillance System
9	Supply Chain Integrity
10	Local Standards
11	International Standards

As illustrated in Figure 5, there are 2 Domains - **Scientific and Engineering Principles (SE)** and **Regulatory Principles (RP)** in the dimension of **General Technical Competencies.** All competencies in this dimension have averaged scores over 4.1/5 (either Primary Focus or Secondary Focus) as illustrated in the figure.

Nine (9) out of twenty (20) General Technical Competencies are rated as most critical, or **Primary Focus,** and all of them in the Domain of Regulatory Principles (RP). This shows regulators are, in general, more inclined to prioritize trainings for competencies in regulatory principals such as Risk Classification, Combination & Borderline Products, Unique Device Identifier (UDI), Standards, Essential Principles of Safety & Performance, etc. While Scientific & Engineering Principles are obviously deemed important (no score was below 4.1/5), however, these could be trained through standard curricula outside regulatory agencies, such as universities, professional association, or training agencies. This may also explain the reason why none of the competencies within the domain of Scientific and Engineering Principles was rated as most critical (with scores above 4.4/5), or Primary Focus.

AHWP member economies currently undertake different activities across the medical device product lifecycle. A majority of economies focus on pre-market and post-market control, whilst a minority of economies invest in regulatory lab testing.

It is key to first understand the scope of work of regulators in different economies before identifying core competences essential for them to perform optimally. The survey questions were grouped into 6 Domains: 1-Pre-market evaluation, 2-Clinical oversight, 3-Laboratory testing, 4-Manufacturing control, 5-Distribution control, and 6- Post-market Monitoring. And within each of the 6 Domains, regulators were asked to identify the current scope of regulatory activities within their agency before rating the importance of the competencies within these Domains.

The findings of these 6 survey questions are instrumental in better understanding and interpreting the variations in the work scope of regulators across different economies. They also corroborate the need for dividing functional competencies into different modules, which can be selected according to regulators' current practices or near-term needs.

In the survey, for each of the 6 Domains, regulators were asked to identify:

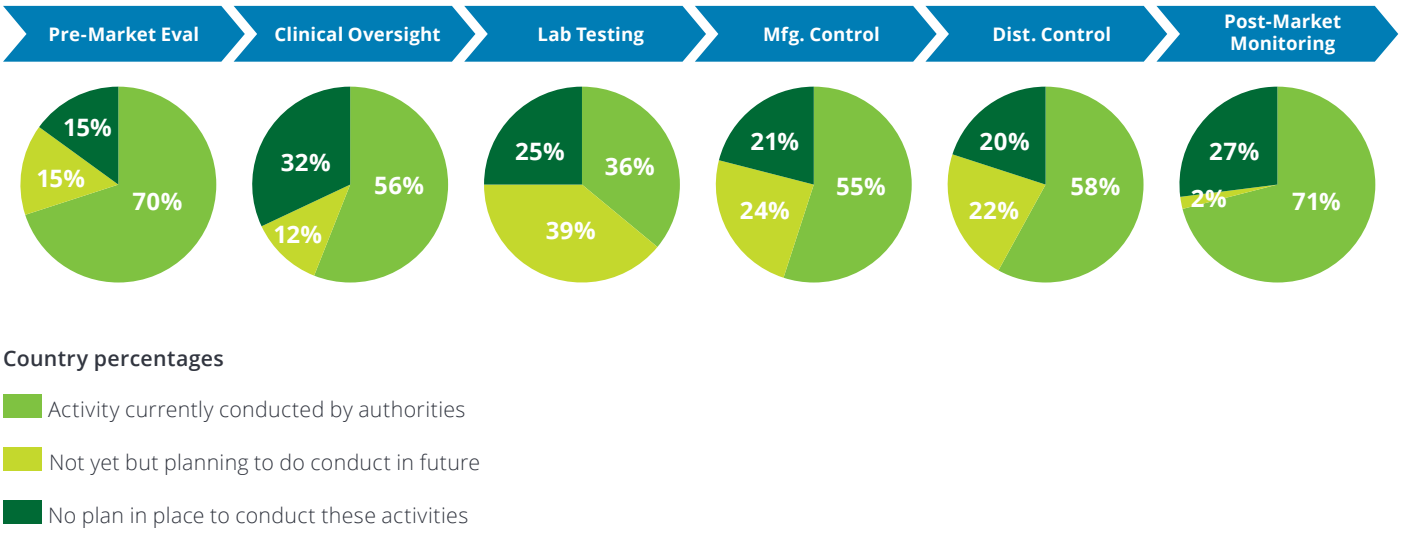
- Regulatory activities which are currently conducted by the regulatory agency;
- Regulatory activities which are not yet conducted by the agency but will be in the near future;
- Regulatory activities which are not conducted by the agency, and where there is no plan to do so.

As shown in Figure 6, about 70% of the surveyed economies are currently implementing Pre-Market Control and Post-Market Monitoring, and an additional 15% are planning to implement Pre-Market Monitoring.

About half of the surveyed economies have regulatory controls over clinical evaluation, manufacturing and distribution. An additional 20% are planning to invest in regulating manufacturing and distribution, while an additional 12% are planning to regulate clinical evaluation.

Only 36% of participating economies are currently conducting regulatory lab testing, but another 39% (the biggest increase across all functions) are planning to invest in this regulatory activity and thus might be keener in enhancing their capacities in this field.

Figure 6. Regulatory Activities Undertaken Across Markets & Medical Device Life Cycle.



As shown in Figure 7, in the dimension of **Functional Technical Competencies,** there are 6 Domains based on the product lifecycle regulation, including:

- Pre-market evaluation (PM)
- Clinical Oversight (CO)
- Laboratory Testing (LT)
- Manufacturing Control (MC)
- Distribution Control (DC)
- Post-market Monitoring (PM)

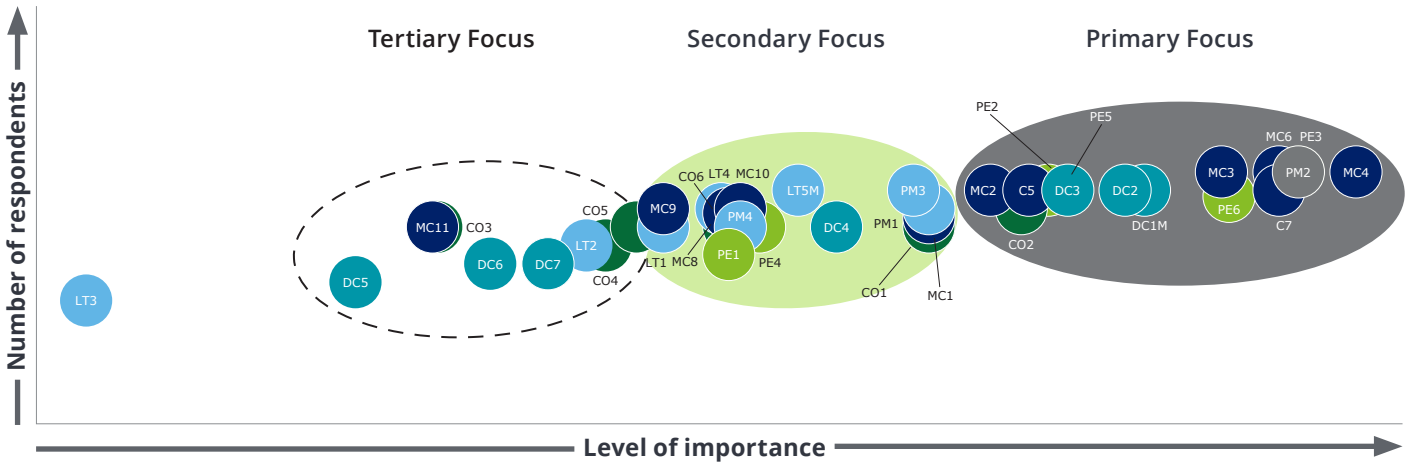
Fifteen (15) out of thirty-nine (39) Functional Technical Competencies were rated as most critical or Primary Focus. For example, Pre-Market Evaluation (PM), most regulators considered knowledge of grouping, submission dossier format & content, change management, and general safety & performance evaluation to be the most important.

Similar with Pre-Market Evaluation, all competencies in the domain of Post-Market Monitoring were also rated with averaged scores over 4.1/5. The domain of Manufacturing control (MC) has the largest number of competencies that were rated as Primary Focus, including both local and international GMP requirements, Quality System auditing, validation and verification methods, risk management methods, etc.

Consistent with findings from Figure 6, where lab testing attracted the least investment among regulators currently, none of the competencies under Laboratory testing (LT) was rated as the most critical or Primary Focus based on the regulators' self-assessment.

MedTech regulators are recommended to focus on competencies that are relevant to their current scope of work but are also recommended to build their internal talent pipeline according to the long-term and short-term plans of the regulatory system or agencies.

Figure 7. Prioritization of Functional Technical Competencies.



Pre-Market (PM)	Clinical Oversight (CO)	Laboratory Testing (LT)	Manufacturing Control (MC)	Distribution Control (DC)	Post Market (PM)
1 International MD Rqmts.	1 Declaration of Helsinki & Nuremberg Code	1 Good Laboratory Practice	1 Intl. MD Rqmts. In Quality system (QS)	1 Good Distribution Practice	1 Intl. MD Reqmts. in Post-marketing Surveillance
2 Device Registration Unit / Grouping Principles	2 ISO 14155 Clinical Investigation of MD for Human Subj.	2 Laboratory Quality Management System	2 GMP (loc.)	2 Quality System Auditing Skills	2 Risk Management Principles
3 Submission Dossier Format and Content	3 Good Clinical Practice (ICH)	3 Occupational Health and Safety Standards	3 GMP(Intl.)	3 Risk Management Principles	3 Advertising & Promotional Regulation
4 Declaration of Conformity Rqmts.	4 Good Clinical Practice (Local)	4 Relevant Local Test Standards	4 QS Auditing Skills	4 Import/Export Regulations (loc.)	4 Supervision on Reprocessing of Single-use Medical Devices
5 Device Change Management	5 Clinical Evaluation (Evidence Based)	5 Relevant International Test Standards	5 Loc./Intl. Standards	5 Import/Export Regulations (Intl.)	
6 General Device Safety & Performance	6 Statistics		6 Design Validation / Verification Methods	6 Disposal of MDs	
			7 Risk Mgmt. Principles	7 Environmental Considerations	
			8 Mfg.Process & Tech.		
			9 Calibration/ Metrology		
			10 Cleanroom Process		
			11 Refurbishment of MDs		

Chapter 4
Introducing the Medical Technology Regulator's Competency Framework

Using the findings from the surveys, this paper lays out a Competency Framework for MedTech Regulators built on the following building blocks:

A. Competencies, which represents skills, knowledge, and behaviours of MedTech Regulatory authority staff that demonstrate an ability to perform the job requirements of the specific **"domain".**

B. Domain, which documents functions, roles, and proficiencies within a MedTech regulatory agency.

a. "Foundational" domain emphasises the overarching roles and activities required by MedTech regulators as a whole. This domain includes the following areas:

- Legal
- Operation
- Communication
- Management
- Multisector Partnership
- Industry Insights

b. "General Technical" domain relates to the nature of training and the technical proficiency required to exercise effective control throughout the medical device life cycle. It includes the following areas:

- Scientific & Engineering Principles
- Regulatory Principles

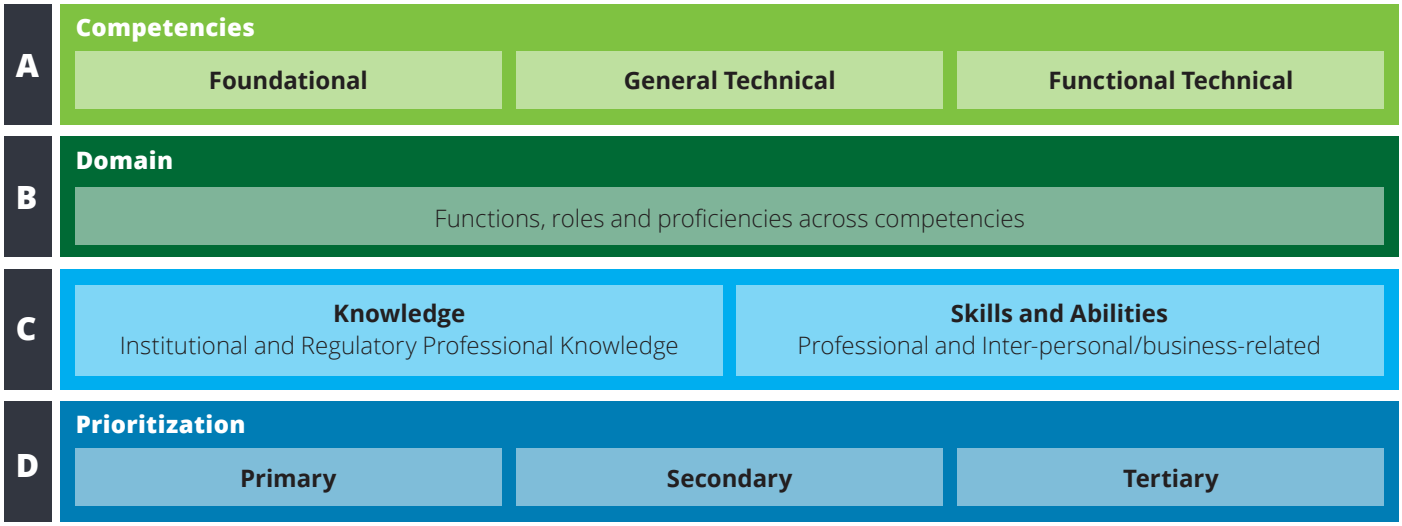
c. "Functional Technical" domain emphasizes the application of knowledge and skills needed to perform effectively in a specific function of the medical device life cycle regulation. It includes the following areas:

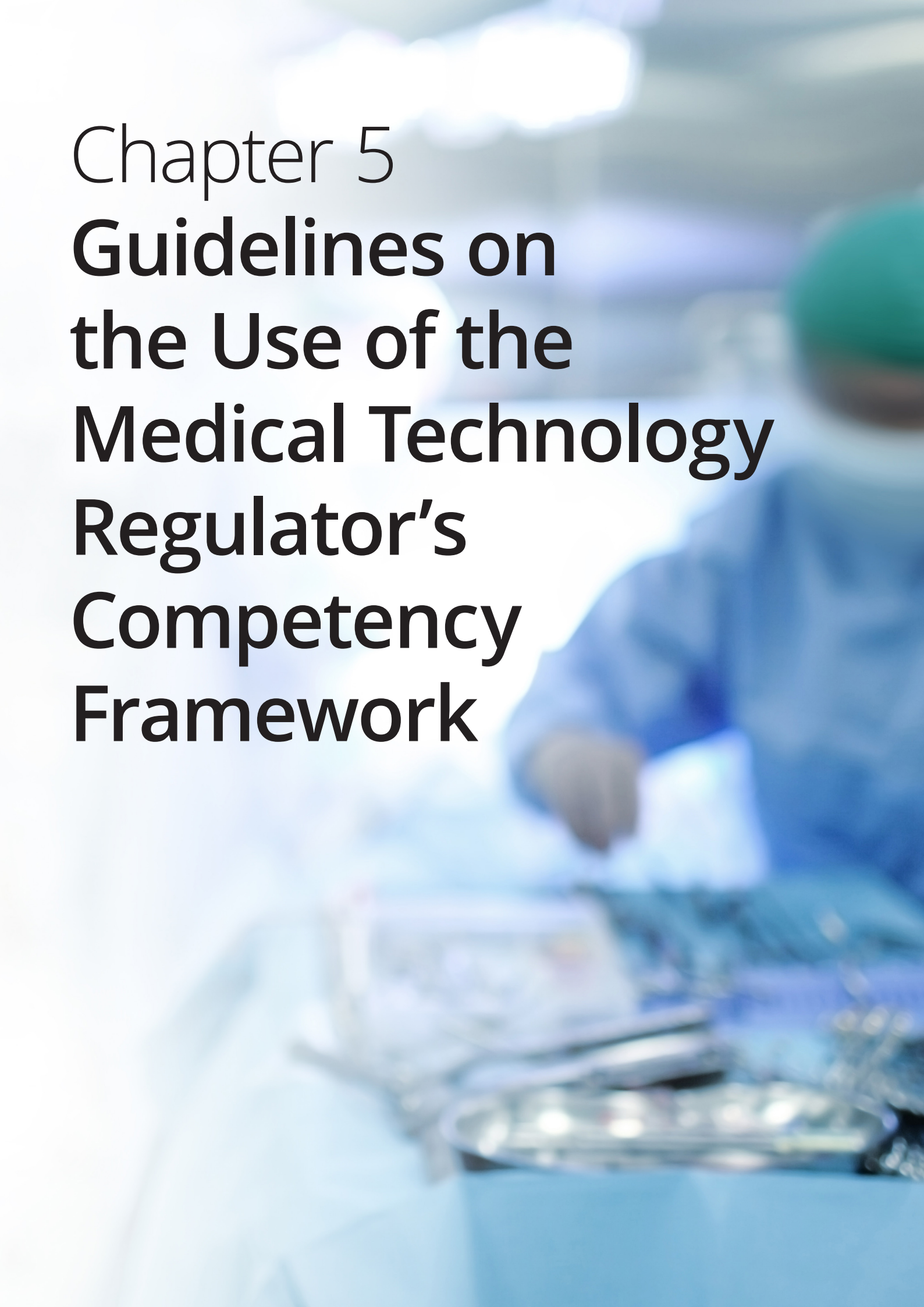
- Pre-market Evaluation
- Clinical Oversight
- Laboratory Testing
- Manufacturing Control
- Distribution Control
- Post-market Monitoring

C. Knowledge, skills and abilities, demonstrate on-the-job behaviour of competence across specific domains.

D. Prioritisation, suggests recommended focus areas for developing a holistic Training Curriculum to improve "knowledge, skills and abilities" of MedTech regulators.

Figure 8. MedTech Competency High-Level Framework.





Chapter 5
Guidelines on the Use of the Medical Technology Regulator's Competency Framework

This framework provides a detailed description of ninety-seven (97) competencies, including thirty-eight (38) foundational competencies, twenty (20) general technical competencies, and thirty-nine (39) functional technical competencies for MedTech regulators across different economies. It is recommended that MedTech regulators and multiple stakeholder could use this framework as a starting point to develop the regulatory curriculum after conducting gap assessment based on current scope of work as well as future needs.

Using the Framework

Step 1:
Select competency category. It is recommended MedTech regulators and their trainings partners review this competency framework category by category, starting from Foundational Competencies (Figure 9), to General Technical Competencies (Figure 10), then to Functional Technical Competencies (Figure 11).

Step 2:
Select level of focus. Prioritize trainings based on the level of focus, starting from "Primary" competencies, followed by "Secondary", finally to "Tertiary" competencies, resources permitting.

Step 3:
Identify the curriculum framework based on competency framework and gap assessment. It is recommended to identify the competencies that are relevant and critical to the trainees in the regulatory agency and to formulate the curriculum framework based on gap assessment and both short-term and long-term needs.

Step 4:
Develop training programs. It is recommended for MedTech regulators to involve multiple stakeholders from both public and private sectors as early as possible in identifying the needs and prioritizing the trainings resources. Subject experts should be invited to advise on developing trainings programs, delivering trainings as well as evaluating the effectiveness of trainings.

Figure 9. Prioritization of Foundational Competencies.

Priority	Domain	Knowledge, Skills and Abilities
Primary	Legal	• Legal Documents (Local) • Technical Documents (Local)
	Management	• Good Regulatory Practice • Quality Management System for Regulatory Authorities • Risk Management • Training
	Operation	• Code of Conduct • Documentation & Filing • Technical Report Writing
	Communication	• Effective Communication (verbal and written) • Interpersonal Skills
	Industry Insights	• Emerging Technologies and Products
Secondary	Management	• People Management • Leadership • Crisis Management • Mentoring & Coaching • Policy Analysis & Strategies
	Communication	• Public Education • Negotiation • Public Speaking • Information Dissemination & Media Strategy
	Industry Insights	• Local Industry Landscape • International Industry Landscape
	Operation	• Critical Thinking & Problem Solving • Customer Service • IT Skills
	Multi-Sectoral Partnership	• International Initiatives and networks • Stakeholder Engagement • Public Health
	Legal	• Legislative process

Priority	Domain	Knowledge, Skills and Abilities
Tertiary	Management	• Project Management
	Operation	• Budget Planning & Management
	Legal	• Legal Documents (International) • Technical Documents (International) • Legal Writing
	Multi-Sectoral Partnership	• Diplomatic and Foreign Affairs Policy • Foreign Languages & Culture • Healthcare Ecosystem

Figure 10. Prioritization of General Technical Competencies.

Priority	Domain	Knowledge, Skills and Abilities
Primary	Regulatory Principles	• Essential Principles of Safety & Performance • Conformity Assessment Concepts and Principles • Combination and Borderline Products • Post-marketing Surveillance System • Risk Classification • Local Standards • Differences between Pharmaceuticals, General MDs and IVDs • Device Labelling & Unique Device Identifier (UDI) • International Standards
Secondary	Regulatory Principles	• Supply Chain Integrity • Device Nomenclature Systems (GMDN/UMDNS)
	Scientific Engineering Principles	• Biomaterials • Radiation and Nuclear Medicine • Biological Science • Human Anatomy and Physiology • Biochemistry • Biomechanics • Digital Technology (mobile health, telemedicine, AI, etc.) • Nanomaterials • Bioelectronics

Figure 11. Prioritization of Functional Technical Competencies.

Priority	Domain	Knowledge, Skills and Abilities
Primary	Manufacturing Control	• Quality System Auditing Skills • Design Validation and/or Verification Methods • Risk Management Principles • Good Manufacturing Practice (International) • Relevant Local and International Standards • Good Manufacturing Practice (Local)
	Premarket Evaluation	• Submission Dossier Format and Content • General Device Safety & Performance • Device Registration Unit/Grouping Principles • Device Change Management
	Post-Market Monitoring	• Risk Management Principles
	Distribution Control	• Good Distribution Practice • Quality System Auditing Skills • Risk Management Principles
	Clinical Oversight	• ISO 14155 Clinical Investigation of MD for Human Subjects
Secondary	Manufacturing Control	• Manufacturing Process & Technology • International Medical Device Requirements in Quality System • Cleanroom Processes • Calibration and Metrology
	Clinical Oversight	• Declaration of Helsinki & Nuremberg Code • Statistics
	Post-Market Monitoring	• International Medical Device Requirements in Post-marketing Surveillance • Advertising and Promotional Regulation • Supervision on Reprocessing of Single-use Medical Devices (SUMDs)
	Distribution Control	• Import/Export Regulations (including customs requirements - Local)
	Laboratory Testing	• Relevant International Test Standards • Relevant Local Test Standards • Good Laboratory Practice
	Premarket Evaluation	• Declaration of Conformity Requirements • International Medical Device Requirements in Premarket Evaluation
Tertiary	Manufacturing Control	• Refurbishment or Reprocessing of Medical Devices
	Laboratory Testing	• Occupational Health and Safety Standards • Laboratory Quality Management System
	Clinical Oversight	• Clinical Evaluation (Evidence Based Medicine) • Good Clinical Practice (Local) • Good Clinical Practice (ICH)
	Distribution Control	• Environmental Considerations • Disposal of Medical Devices • Import/Export Regulations (including customs requirements - International)

About **AHWP**

Asian Harmonization Working Party (AHWP) is established as a non-profit organization. Its goals are to study and recommend ways to harmonize medical device regulations in the Asian and other regions and to work in coordination with the Global Harmonization Task Force, 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 Asian and other regions that support the above stated goals.

About **APACMed**

Established in 2014, the Asia Pacific Medical Technology Association (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 the Asia Pacific. APACMed is the first and only regional association to provide a unified voice for the medical technology industry in the Asia Pacific. APACMed works proactively with bilateral, regional and local government bodies to shape policies, and demonstrate the value of innovation and promote regulatory harmonization. APACMed engages with medical device associations and companies in the Asia Pacific to advance regional issues, code of ethics and share best practices.

About **Deloitte Southeast Asia**

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We trust that this paper will be valuable for regulators as they develop actionable plans to address the competency capability challenge faced across APAC, and ultimately deliver high-quality services to all the stakeholders they collaborate with.

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