Competency Framework for MedTech Regulators

A joint initiative of AHWP, APACMed, and Deloitte

Acknowledgments

We would like to give special thanks to MedTech regulatory agencies from the 13 AHWP economies for their participation in the self-assessment survey, the results of which provided the foundation to this competency framework. The economies include 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.

We would like to especially thank the leadership of Mr. Ali M. Al-Dalaan, Chair of AHWP Technical Committee, Dr. Jeong-Rim Lee, Director of Korea Ministry of Food and Drug Safety (MFDS), and Mr. Alfred Kwek, AHWP Technical Committee Co-Chair (Industry).

Finally, we are grateful to all APACMed member companies for their valuable participation in the industry survey, which provided great value in validation of the methodology of this study.

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

Agenda

- ❑ Introduction
- ❑ Key findings from survey
- ❑ MedTech Regulators' Competency Framework

Introduction

Rationale

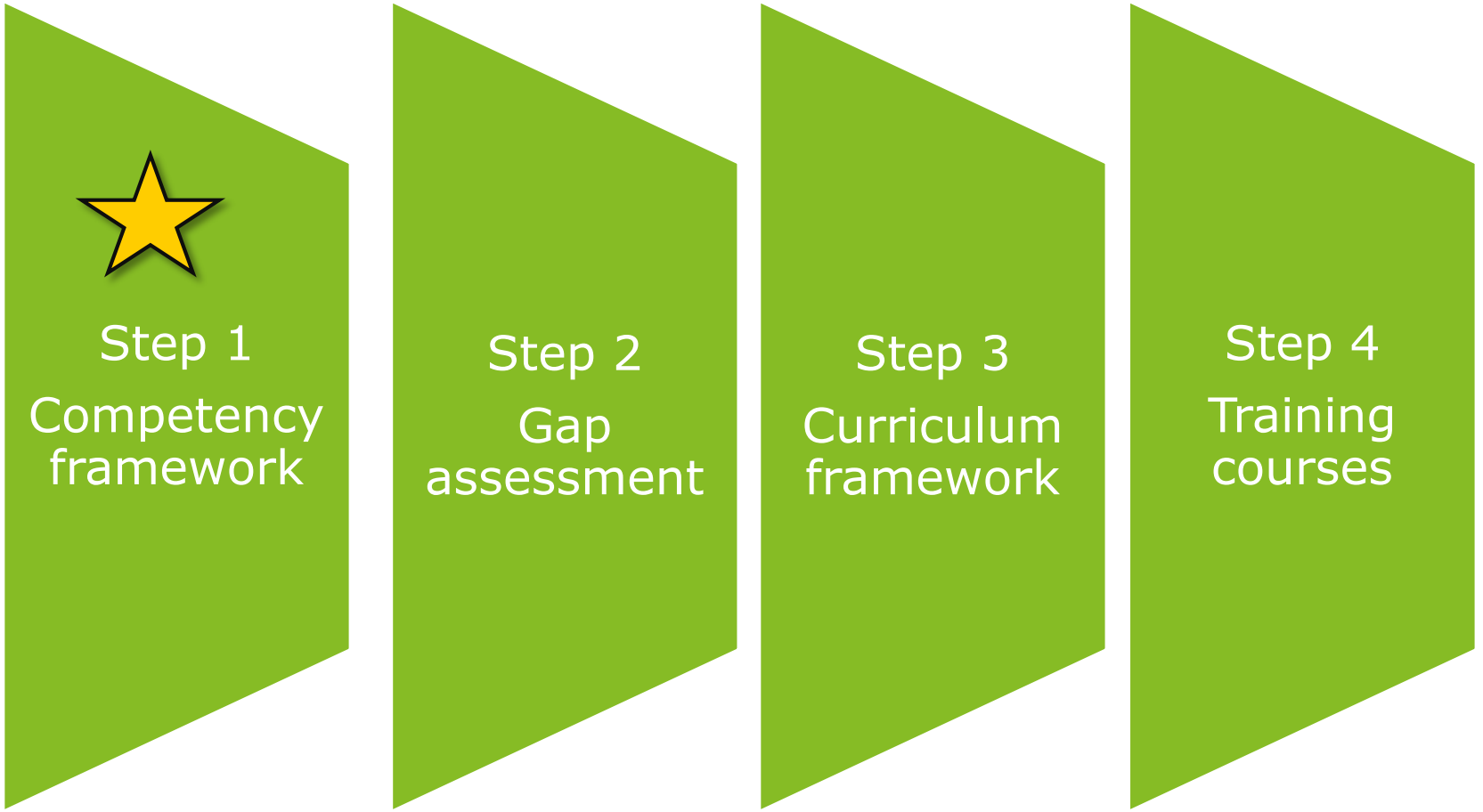
Over the last decades, international organizations, government agencies, NGOs, academia, associations, and industry have come together to build a sustainable talent pipeline of regulatory professionals across both sectors.

However, the efficiency and effectiveness of these efforts have been questioned. 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.

It takes 4 steps to design good trainings

Scope of this project



AHWP/APACMed/Deloitte joint study methodology

1 **Identify structure and key activities of regulatory authorities** from multiple sources, e.g. WHO, IMDRF/GHTF, AHWP, MDA, etc.

2 **Develop initial hypotheses on the 3 categories of competencies** that are most important and relevant for MedTech Regulatory Authorities' capacity building efforts

3 **Validate initial hypotheses** by incorporating insights from AHWP/APACMed/Deloitte working group

4 **Draft survey questions** for MedTech Regulatory Authorities and companies

5 **Launch 2 sets of surveys:**

- Self-assessment by MedTech regulatory authorities from AHWP economies
- Survey in MedTech companies for their expectation of regulatory authorities' competences

6 **Develop Regulator Competency Framework** by analyzing responses from 2 sets of surveys and validating it within the AHWP/APACMed/Deloitte working group

We are here today

7

Finalize Competency Framework for MedTech regulatory authorities

Run webinar to present the finalized Competency Framework

Develop White-paper

Final deliverable

Secondary Research

*Regulatory Mode*l based on five economies of Global Harmonization Task Force (GHTF);

Asian Harmonisation Working Party (AHWP) Playbook for Implementation of Medical Device Regulatory Frameworks focusing on regulatory controls on importers and distributors;

World Health Organisation (WHO) Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices, which provides a segmentation of regulatory activities at basic level and expanded level;

WHO global benchmarking tool with 4 maturity levels of regulatory functions;

Medical device regulatory competency program in Malaysia.

Primary Research

Regulator's self assessment

To identify the scope of regulatory activities in AHWP member economies;

To 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).

Industry Survey

To assess their current levels of satisfaction with the overall levels of knowledge and service of MedTech Regulators;

To assess their expectations of regulators' competencies and skill set for validation purpose.

Two surveys were launched in July and August of 2018 which formed the basis of this study

We reached out to MedTech regulatory agencies of 30 AHWP Member Economies…

What?

Uncover common Regulator internal priorities, challenges and focus areas for competency building

Who?

AHWP Regulators of member economies

Self Assessment

+

…and APACMed member companies operating in the identified AHWP Member economies

Stakeholder Expectation

What?

Explore MedTech company stakeholder expectation of AHWP Regulators

Who?

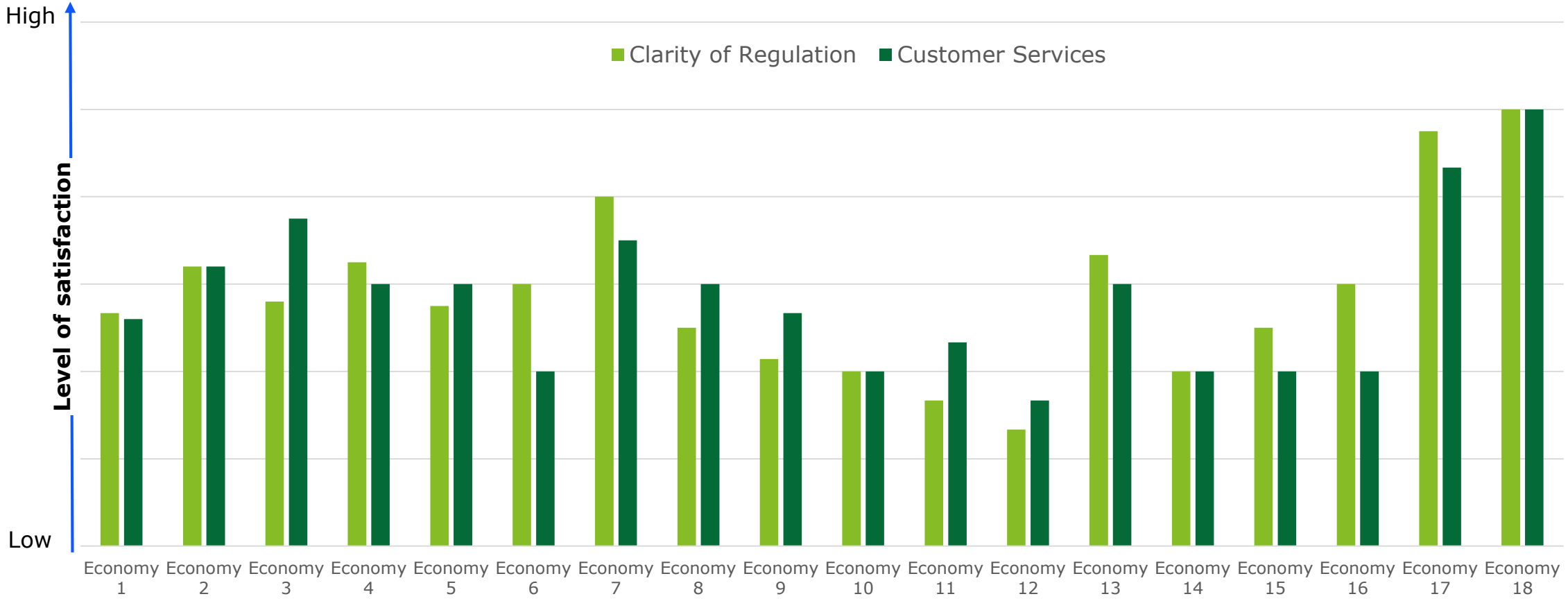
Cross-functional stakeholders from MedTech industry

We have received inputs from 18 MedTech companies and 13 regulatory agencies; subsequent slides describe the key findings from these surveys and a proposed competency framework for MedTech regulatory agencies in AHWP member economies

Key findings from survey

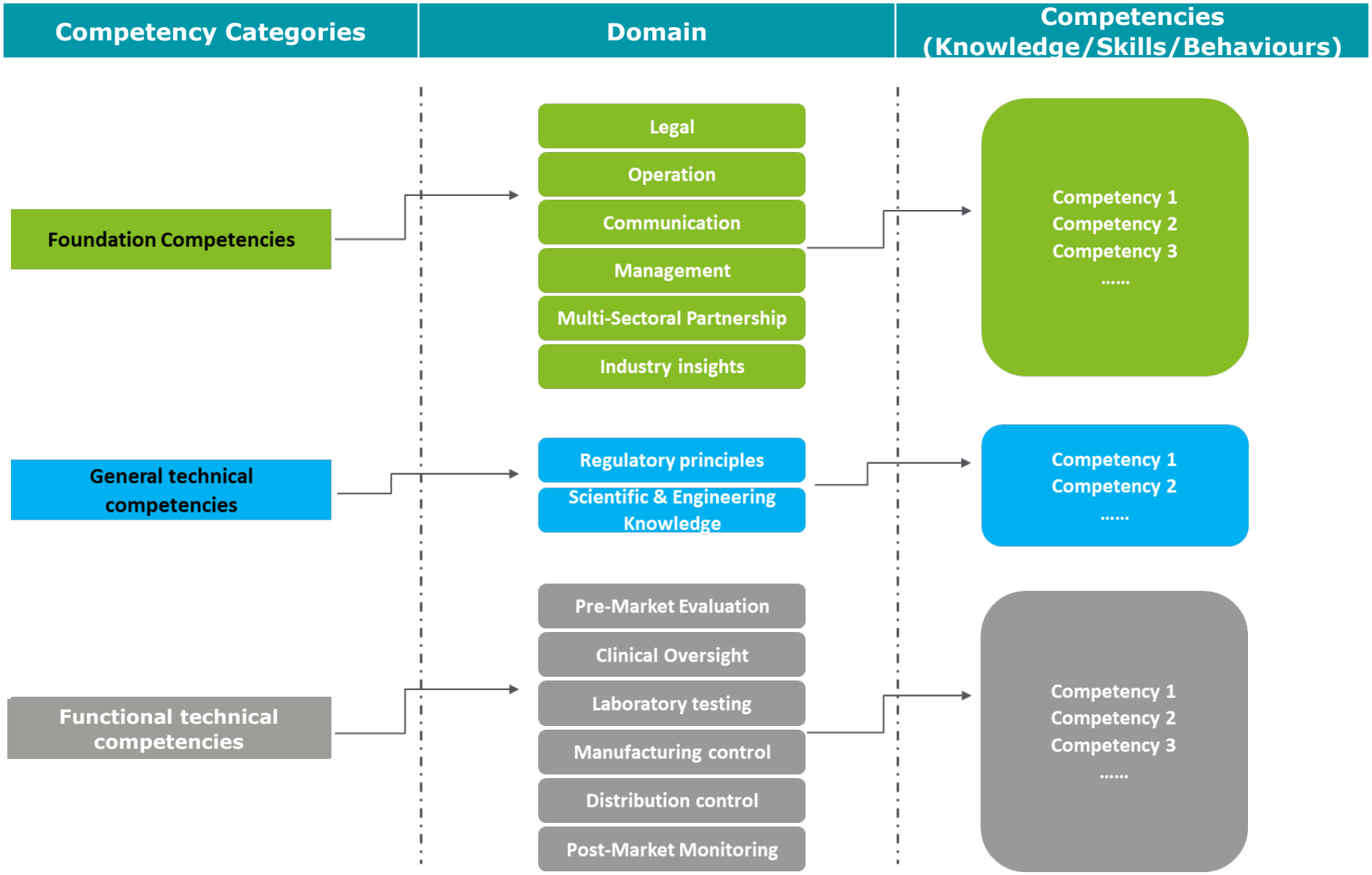
As reported by MedTech companies, satisfaction on customer service has a wide spread but tends to be closely co-related to clarity of regulations in member economies.

MedTech companies gives high value to clarity of regulations and it is one of drivers for improving customer satisfaction



Note: The data is based on MedTech companies survey response for the 18 economies

Structure of the competency framework



Subsequent section illustrates key findings from the self assessment survey of regulatory agencies. These findings have been used to recommend a **competency framework for regulators to conduct gap assessment and develop a training curriculum**

The study acknowledges that constraints and needs vary across AHWP member economies. Hence recommended priority can be used as **a guide and further tweaked to suit individual member economy needs**

Breakdown of competencies & ratings of importance

97 competencies were grouped into three dimensions or categories:

38 **Foundational Competencies** (applicable to all staff)
20 **General Technical Competencies** (applicable to all technical staff)
39 **Functional Technical Competencies** (applicable to staff in a specific regulatory function out of the entire 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) (with score between 4.1/5 to 4.4/5)

Tertiary focus (highlighted in white) (with score less than to 4.1/5)

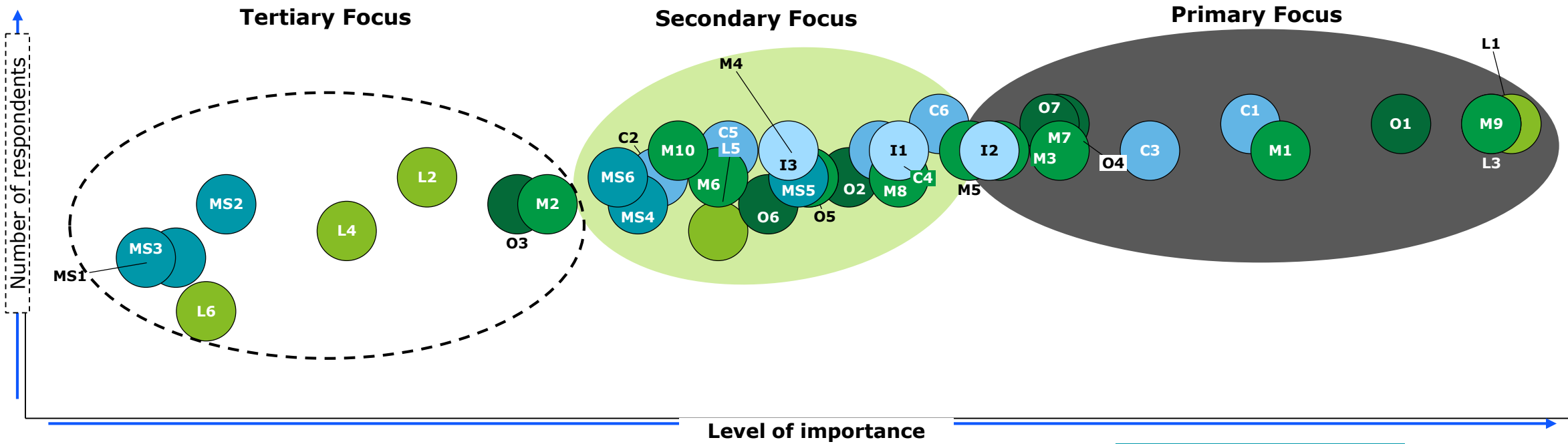
“Foundational Competencies”

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.

1 "Foundational competency" covers 6 domains

All foundational competencies are considered as important across all economies, three distinct groups of skill-sets emerge across level of importance defining the focus areas



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		

“General Technical Competencies”

Domain Deep Dive:

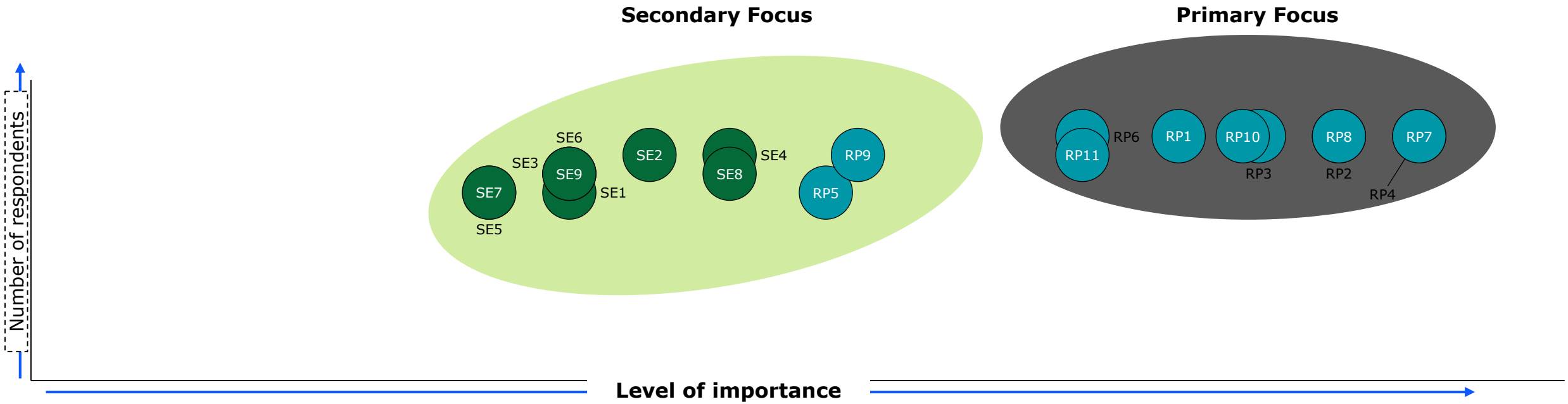
Scientific and Engineering Principles (SE)
Regulatory Principles (RP)

All competencies in this dimension have averaged scores over 4.1/5 (either Primary Focus or Secondary Focus). 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.

2 "General technical competency" covers regulatory principles and scientific/engineering knowledge

All general technical competencies are considered important, mainly two distinct groups of Skill-sets emerge across level of importance defining the focus priorities



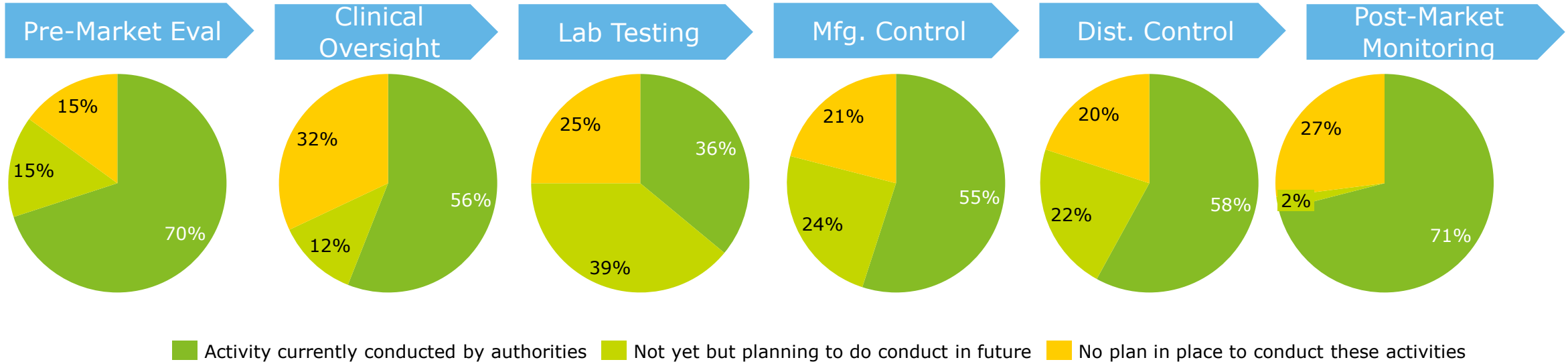
Scientific & Eng. Principles (SE)	
1	Human Anatomy and Physiology
2	Biological Science
3	Biochemistry
4	Biomaterials
5	Nanomaterials
6	Biomechanics
7	Bioelectronics
8	Radiation and Nuclear Medicine
9	Digital Technology (mobile health, telemedicine, AI, etc.)

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

Different regulatory activities throughout the medical device product lifecycle are currently undertaken across markets.

The survey identified key regulatory activities that need to be undertaken across a Medical Device's Lifecycle; Initial assessment suggests a variance in regulatory activities currently undertaken across AHWP Member Economies

- Overall **75%** of the member economies are conducting or planning to conduct regulatory activities across all the product life cycle
- Maturity of providing a full breath of services across the product life cycles varies a lot from economy to economy



Country percentages

Lab testing activities have **limited coverage across** the surveyed member economies

Post market and Pre market evaluation activities have the **highest coverage across** all the functional technical subgroup competencies

"Functional technical competencies"

Domain Deep Dive:

1-Pre-market evaluation, 2-Clinical oversight, 3-Laboratory testing, 4-Manufacturing control, 5-Distribution control, 6-Post-market Monitoring

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.

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.

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.

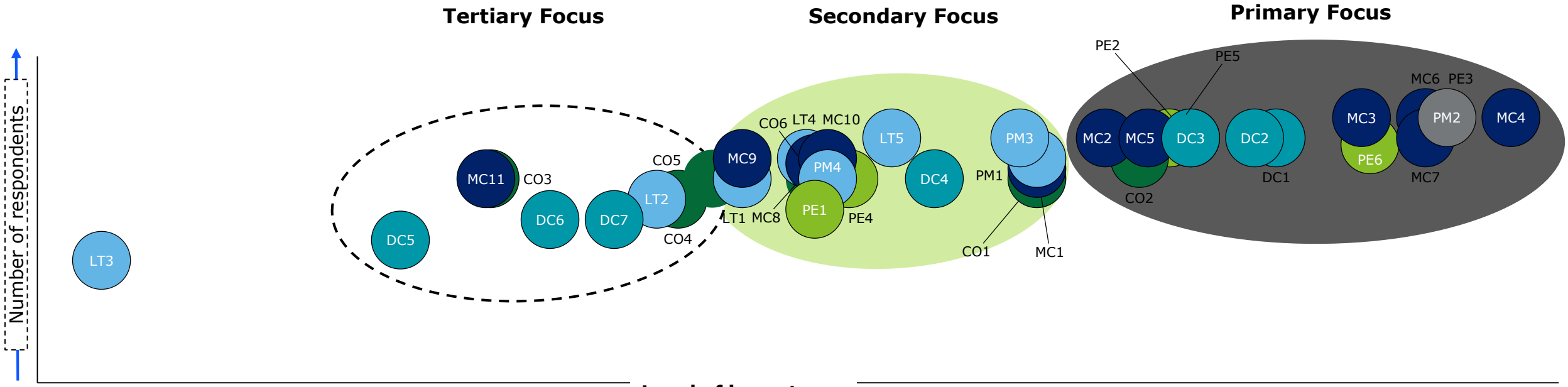
Similar with Pre-Market Evaluation, all competencies in the domain of Post-Market Monitoring were also rated with averaged scores over 4.1/5.

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.

None of the competencies under Laboratory testing (LT) was rated as the most critical or Primary Focus based on the regulators' self-assessment.

3 "Functional Technical competency" cover skills and knowledge required across the product lifecycle

Skills required to undertake regulatory activities across the product lifecycle have been ranked across three distinct groups based on levels of importance by member economies

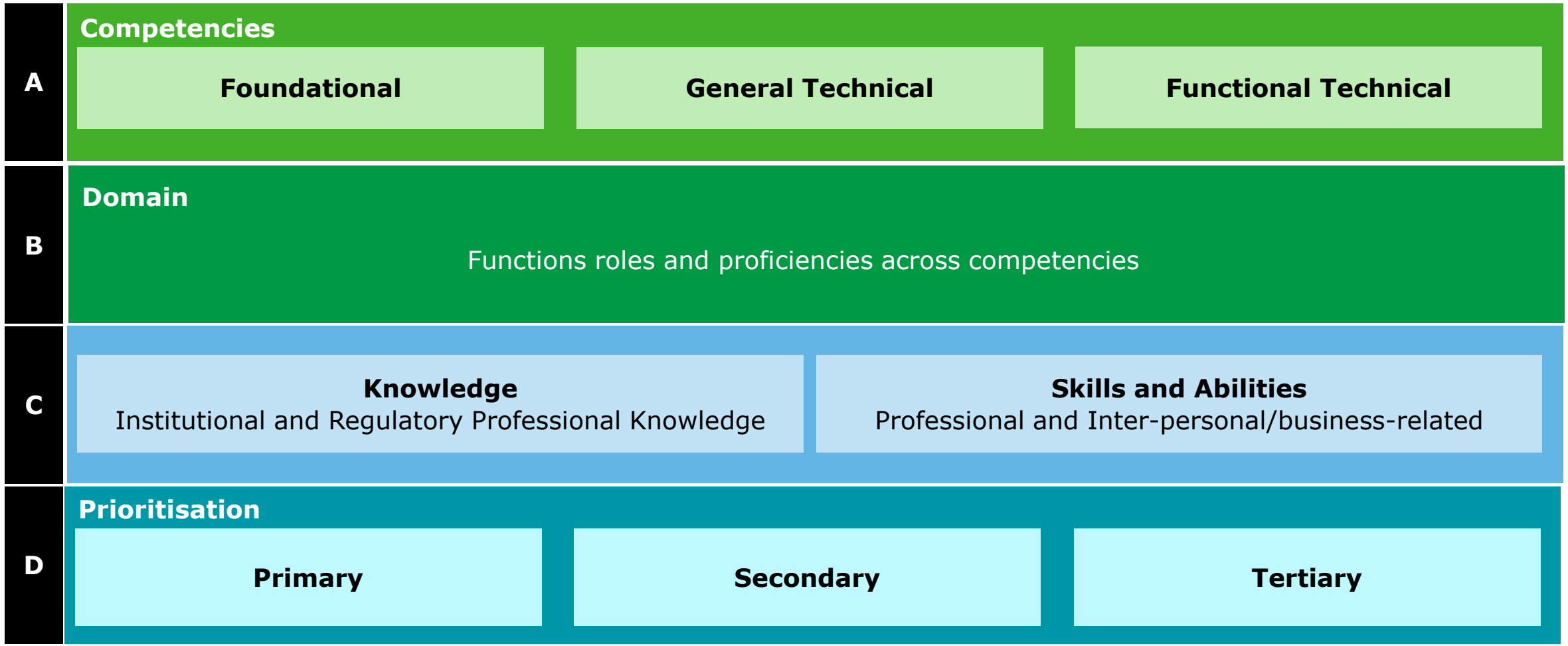


Pre-Market (PM)	Clinical Oversight (CO)	Laboratory testing (LT)	Manufacturing control (MC)	Distribution Control (DC)	Post Market (PM)
1 International MD Rqmts.	1 Declaration of Helsinki & Nuremberg Code	1 Good Laboratory Practice	1 Intl. MD Rqmts. In Quality system (QS)	1 Good Distribution Practice	1 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		

MedTech Regulator Competency Framework

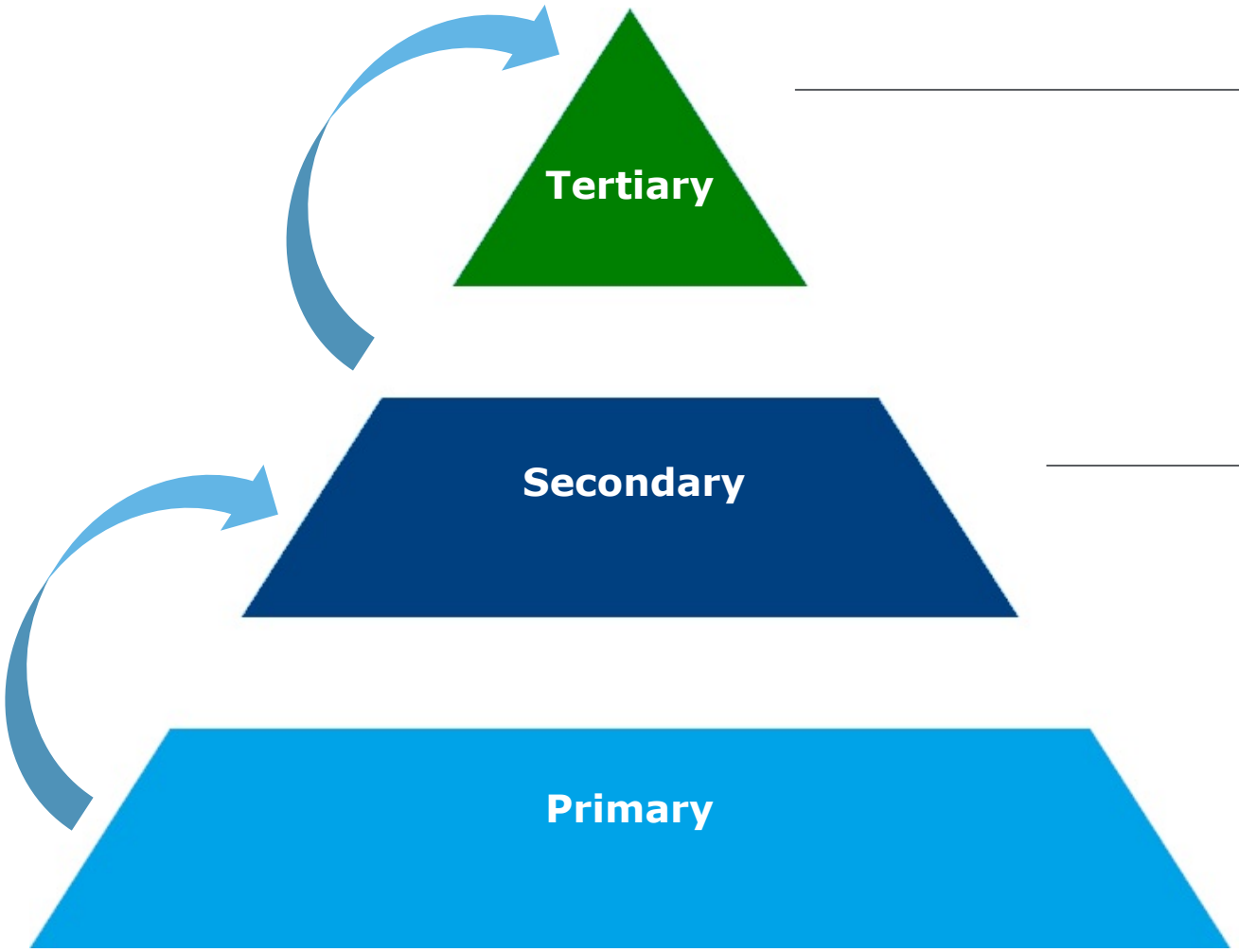
MedTech Competency High-Level Framework

Competencies and associated knowledge, skills and abilities can be developed and supported through a structured training curriculum – the following competency framework with recommended prioritization will assist in conducing gap assessment and developing a training curriculum



Prioritization: Progressive focus areas for competency development

Feedback from regulatory agencies indicate that some skills-sets are more important than others - the framework provides regulators with a clear guidelines on which skills need to be developed first and which need to be developed after



Tertiary competencies will be the final development of skills within individual competency clusters

Secondary focus area of competencies to develop once primary skills are established

Primary focus area of competencies that are most important to focus on a first level within a cluster tier

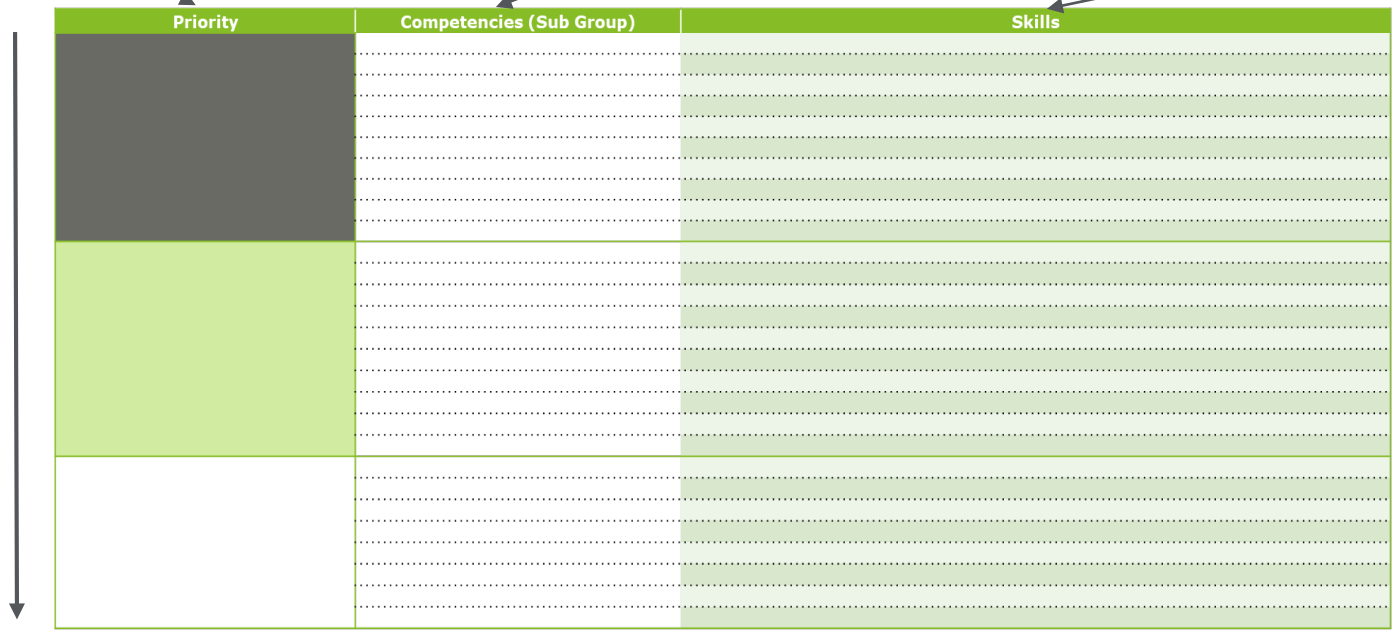
How to read the prioritization table

Competencies and associated skills are arranged according to the level of importance. Regulators can choose to follow recommended priority while developing a training curriculum

1 **Prioritisation** – nomenclature for training prioritization on specific competencies and skills i.e. competencies and skills identified as "Primary" should be considered first, followed by "Secondary" and then "Tertiary"

2 **Competencies** groups have been identified here based on their criticality and importance

3 **Skills** corresponding to Competency sub groups are documented in order of priority to develop a training curriculum on



How to Use 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.

Recommended prioritization for: **Foundational Competencies**

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

Recommended prioritization for: **General Technical Competencies**

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

Recommended prioritization for: **Functional Technical Competencies**

Figure 11. Prioritization of General 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)

Validation of recommended competency prioritization by MedTech Companies (general functional skills[1] only)

MedTech companies rated the skills on level of importance and the results are **80% correlated** with the responses from regulators

MedTech company responses for **Pre-market evaluation, Manufacturing control and Post-marketing** skills sets (on level of importance and criticality) are **100% consistent and co-related** with regulators response

There is **less than 20% variation** between industry practitioners and regulators responses (on level of importance and criticality) for **Clinical oversights, Distribution control and Lab testing** skill sets

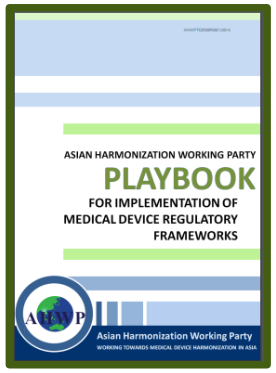
Overall, the proposed framework and prioritisation based on regulators self assessment is 80% co-related with industry practitioner responses

[1] Only 100% completed responses from Industry practitioner is considered for this variance analysis

Enhancing Capacity for Regulatory Agencies and Industries

AHWP Capacity Building Journey

2014 - 2017	2018 - 2019	2020 onwards



KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

BỘ Y TẾ MINISTRY OF HEALTH

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

MINISTRY OF HEALTH OF THE REPUBLIC OF KAZAKHSTAN

สำนักงานคณะกรรมการอาหารและยา
Food and Drug Administration

FDA
Food and Drug Administration
PHILIPPINES

Medical Device Authority
Ministry of Health Malaysia

Deloitte. AHWP Asian Harmonization Working Party APACMed

- White Paper Competency Framework for Medical Technology Regulators
- Webinar

สำนักงานคณะกรรมการอาหารและยา
Food and Drug Administration

Competency Framework for
Medical Technology Regulators

Thailand in-country regulator training – 35 participants

1. *Competency Handbook*
2. *Curriculum*
3. *Training certification*

References

- ***WHO global benchmarking tool (2018)*** http://www.who.int/medicines/regulation/benchmarking_tool/en/

Note 1: Comprehensive categories of indicators with sub-indicators and assigned with 4 different maturity levels

Note 2: For regulatory agency competency rather than regulatory individual competency; more for pharmaceuticals rather than medical devices (WHO has a tool for medical devices under development)

- ***AHWP Playbook for Implementation of MD Reg Framework (2014)***

Note 1: A graduated set of controls – from the most basic to the more advanced – proportionate to device risks and across the medical device life cycle.

Note 2: Focus on regulatory controls of importers and distributors, rather than on those economies which also develop and manufacture devices.

- ***GHTF ad hoc regulatory model (2011)***

Note 1: Progressive Regulatory Framework from basic level, to medium level, to highest level

Note 2: Based on GHTF members (Australia, Canada, EU, Japan, and USA), representing only developed economies

- ***WHO Global Model Regulatory Framework for Medical Devices Including in Vitro Diagnostic Medical Devices (2017)***

Note 1: Solid works done by GHTF, AHWP, IMDRF, and WHO

Note 2: Two levels of breakdowns: basic-level vs. expanded level

- ***Medical device regulatory competency program by Malaysia (MDA)***

Note 1: Both layout of competencies and curriculum

Note 2: Specific to Malaysia legal framework

THANK YOU!

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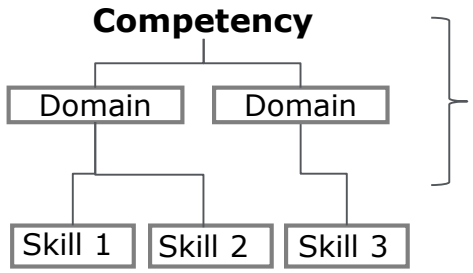
Self-assessment survey for Regulators was to identify scope of regulatory activities and competencies required for the staff



Definition: Behaviours that demonstrate an ability to perform the job requirement competently

Definition: Skills, knowledge and abilities, when incorporated demonstrate an on-the-job behaviour

Three building blocks have been used to identify competencies for the Regulatory Assessment Survey

1

Foundational competencies

Applicable for all staff

Domains:

- Legal
- Operation
- Communication
- Management
- Multi-sectoral engagement
- Industry insights

2

General Technical competencies

Applicable for technical staff

Domains:

- Regulatory Principles
- Scientific and engineering knowledge

3

Functional Technical competencies

Across Product Life-Cycle

Domains:

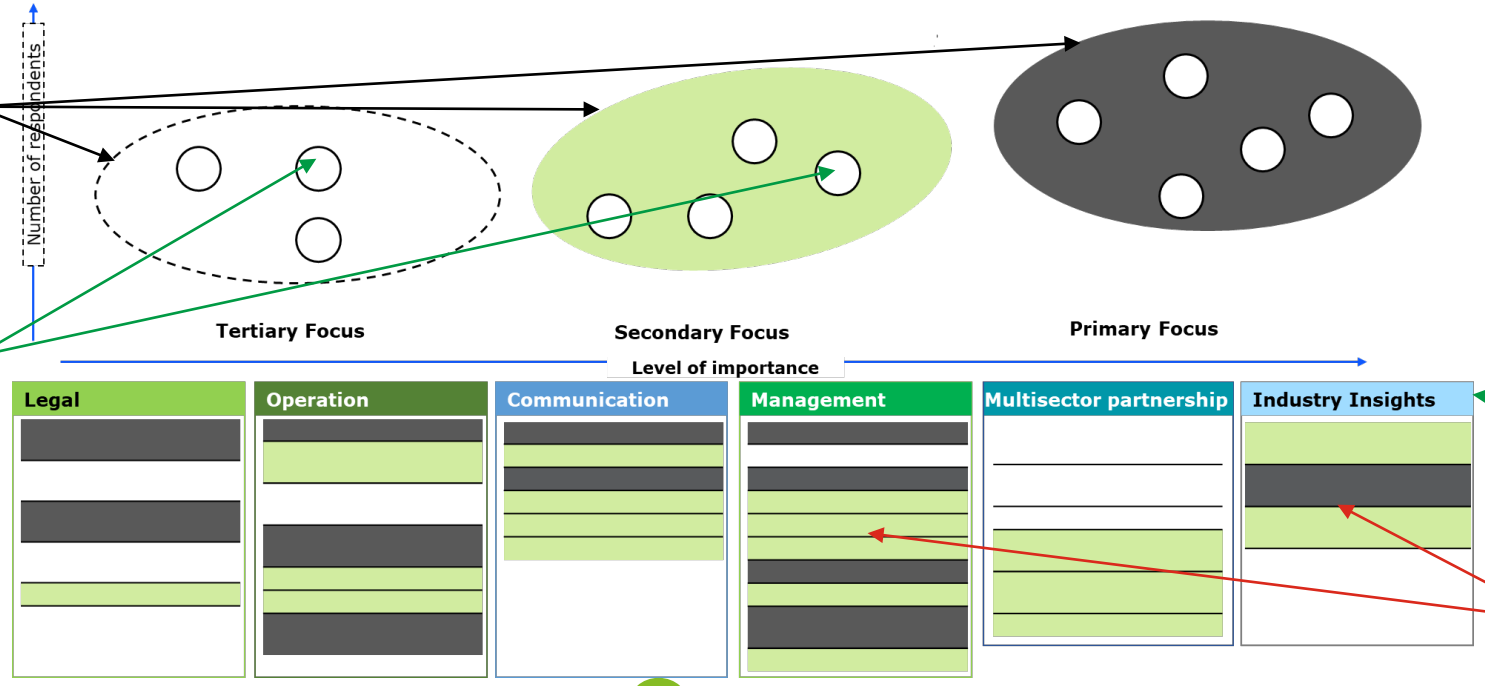
- Premarket Evaluation
- Clinical Oversight
- Laboratory Testing
- Manufacturing Control
- Distribution Control
- Post-market Monitoring

How to read findings from Self Assessment Survey in the framework

The different skills under the competency groupings are scored based on the level of importance provided by regulators. The data was then plotted to identify logical "clusters of skills" that need to be prioritized for training needs. These have been identified as "Primary", "Secondary" and "Tertiary"

1. The skills are grouped together based on their level of importance identified as an area of focus e.g. primary, secondary and tertiary

2. The bubbles represent the Skills in respective primary, secondary and tertiary prioritisation



3. This represents competency sub groups, colours of the box corresponds to the bubble colour

4. This represents skills required by regulators to be performed on the job, colours of the box corresponds to prioritisation of the skills

5. The X-Axis represent the degree of importance of the skills as rated by regulators in their survey

Next Step

- Harmonize the white paper terminology with IMDRF
- Work on the Curriculum for both regulators and industries based on the competencies.

Thank you