Deloitte.

APACMed ASIA PACIFIC MEDICAL TECHNOLOGY ASSOCIATION

Competency Framework for Asia Pacific MedTech Regulatory Professionals

Executive Summary

An aging population, chronic disease prevalence and rising cost of healthcare has led to the growing needs of Medical Technology (MedTech) in Asia Pacific. In addition, MedTech companies are facing numerous difficulties as they seek to serve a large pool of patients coupled with increasing healthcare demands.

In APAC, markets are facing a myriad of challenges, including fragmented regulatory systems, challenging market access issues, and a shortage of regulatory professionals. It is difficult for the regulatory function to compare qualifications, profession experience, and key performance indicators for Regulatory Affairs (RA) professionals across various countries which needs a lot of time and effort. With the ever evolving business and regulatory landscape, existing RA professionals will also need to continuously update and up-skill their regulatory capability to meet those challenges. Hence, a framework with common standards and harmonization of regulatory competencies will increase the effectiveness of regulatory activities.

In an effort to address this dilemma, Asia Pacific Medical Technology Association (APACMed) in collaboration with Deloitte conducted an assessment to identify a Competency Framework that details out the essential competencies required for RA professionals in this region.

APACMed and Deloitte Consulting have jointly conducted surveys on RA capacity building in August 2017 with an aim to define the future direction of regulatory training and development. In addition to the survey, this paper brings together insights from several other sources such as: the Professional Development Framework (PD Framework) of the Regulatory Affairs Professionals Society (RAPS) and learnings from APAC based MedTech companies. This white paper describes the framework along with its potential use. This is achieved by structuring the profession across the following dimensions: professional career levels, domains that reflect stages in the healthcare product lifecycle, the responsibilities and tasks of the RA professional at each step and the associated core knowledge and skills required of the professional. The framework was designed to serve as a catalyst to initiate discussions and collaboration between RA professionals and the associated regulatory bodies.

The imperative - MedTech Regulatory Capacity

Life sciences industry in APAC is set for continued growth and disruption. The positive outlook on Medical Technology (MedTech) companies is driven by several factors, such as an increasing demand from aging population, the prevalence of chronic and communicable diseases, and the uncertainty around healthcare costs and pricing.

MedTech companies are faced with increasing pressure to stay vigilant and competitive to address the increasing healthcare demand. This is especially prevalent in emerging markets of Asia Pacific where MedTech faces a larger challenge given the innovation potential and uncertainty around regulatory compliance.

Today, the ambit of MedTech in this region is experiencing continued growth and is set to surpass the European Union as one of the worlds' second largest MedTech markets by the year 2020[1]. APAC's vastness of terrain, culture and projected growth, are key drivers to these ever increasing health gaps and unaddressed patient needs. However, in order to successfully meet the continued innovation and improvement needs, a greater amount of collaboration between industry and regulators is needed.

Some of the main complexities of achieving this overarching vision are:

- A Fragmented and complex regulatory landscape
  - A complex and fragmented regulatory landscape exists with some fundamental differences such as risk classification of medical devices and registration/approval pathways and processed.
- Limited opportunities for interaction and discussions between regulators and industry RAs
  - There is a limited number of forums available for participants from industry and regulators to engage in constructive discussions and potential collaboration
- Talent shortage, lack of capability development and RA tailored training programs
  - A lack of regulatory capacity to meet the growing demand in the APAC region can lead to longer registration TAT's around registration. This leaves less time for companies and regulators to clarify details around approvals for potential innovations.

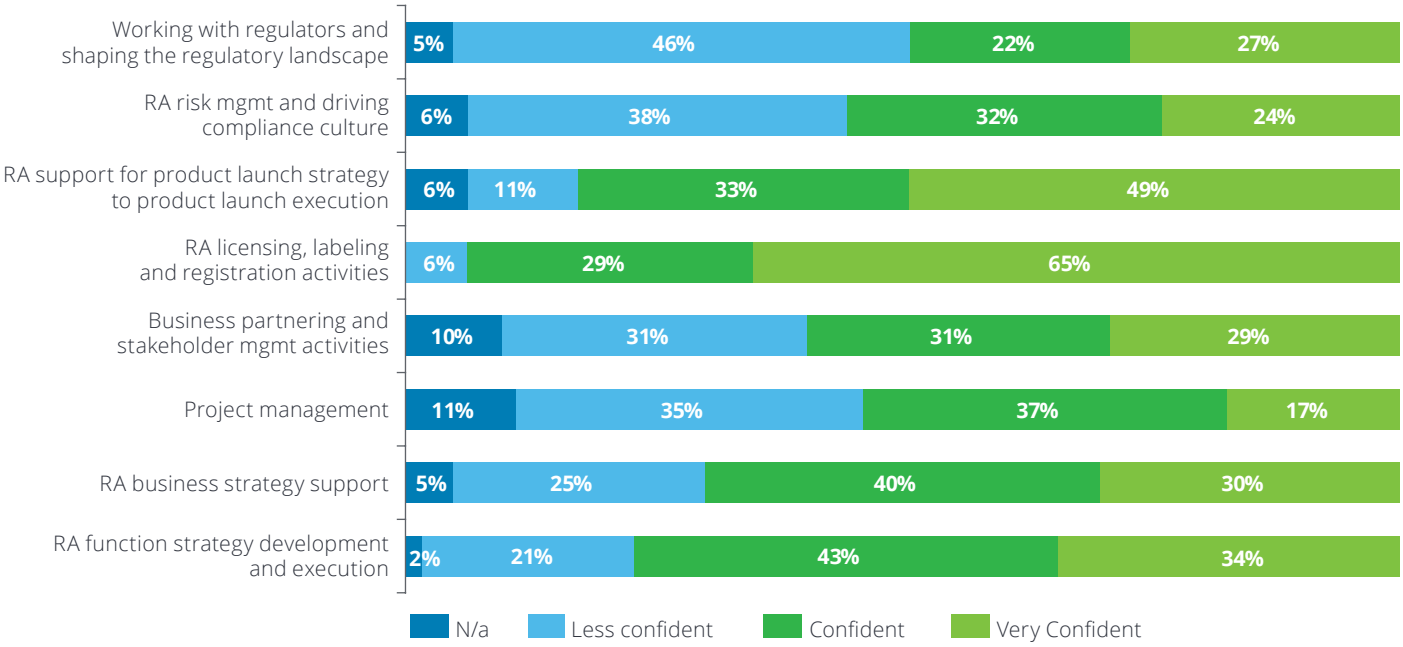
[1] Business Monitor International; GlobalData (Oct 2015)

MedTech RA Survey Key Insights

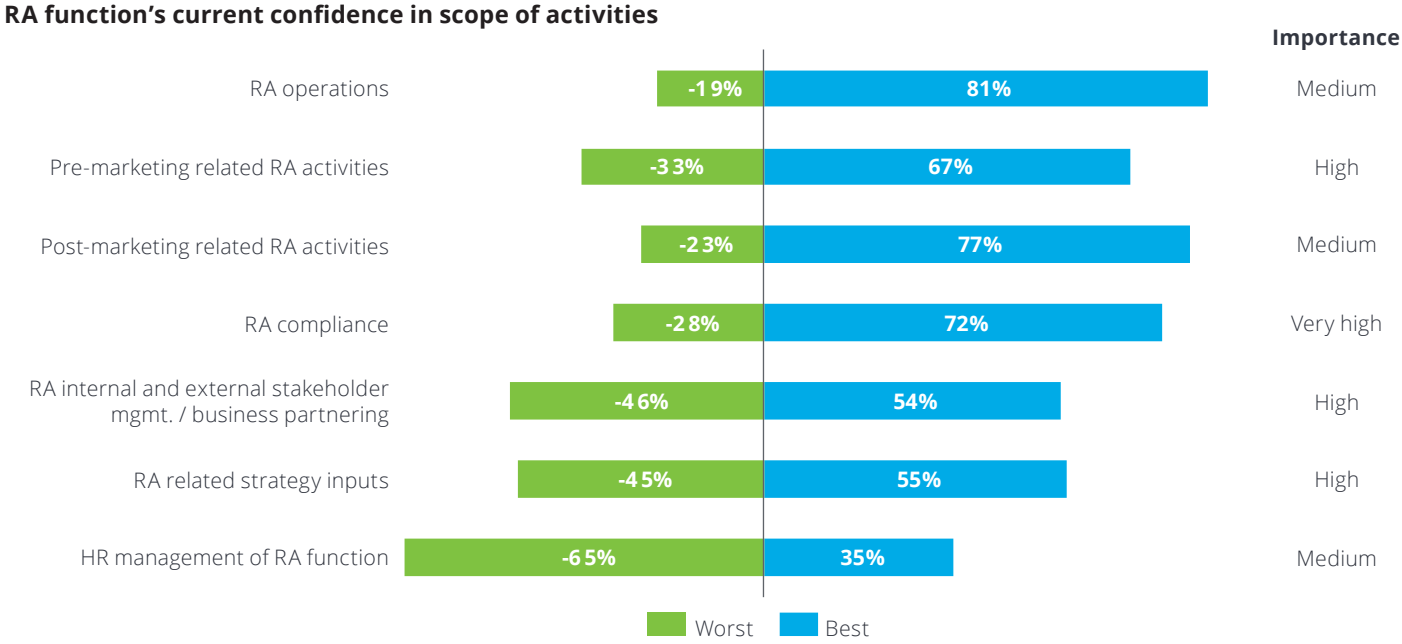
APACMed and Deloitte Consulting have jointly conducted two surveys in August 2017, with an aim to identify the challenges faced by MedTech RAs and get an understanding of the expectations of cross-functional stakeholders from the RA function. The team has received input from 67 RA executives and 63 RA stakeholders from the APAC MedTech sector. The surveys have provided insights into the current RA development needs from both a business standpoint as well as from a skills and competency perspective. Some of the key findings are highlighted below.

- Self-assessment indicated that they are confident in performing most of the **RA function** activities, but less confident in **interacting with regulators** and **managing risks.** This is in line with stakeholders' perception that RA operations and post-marketing activities perform relatively well. Critical activities around stakeholders management and business partnering have a lot of space for improvement.

Ability to perform RA activities



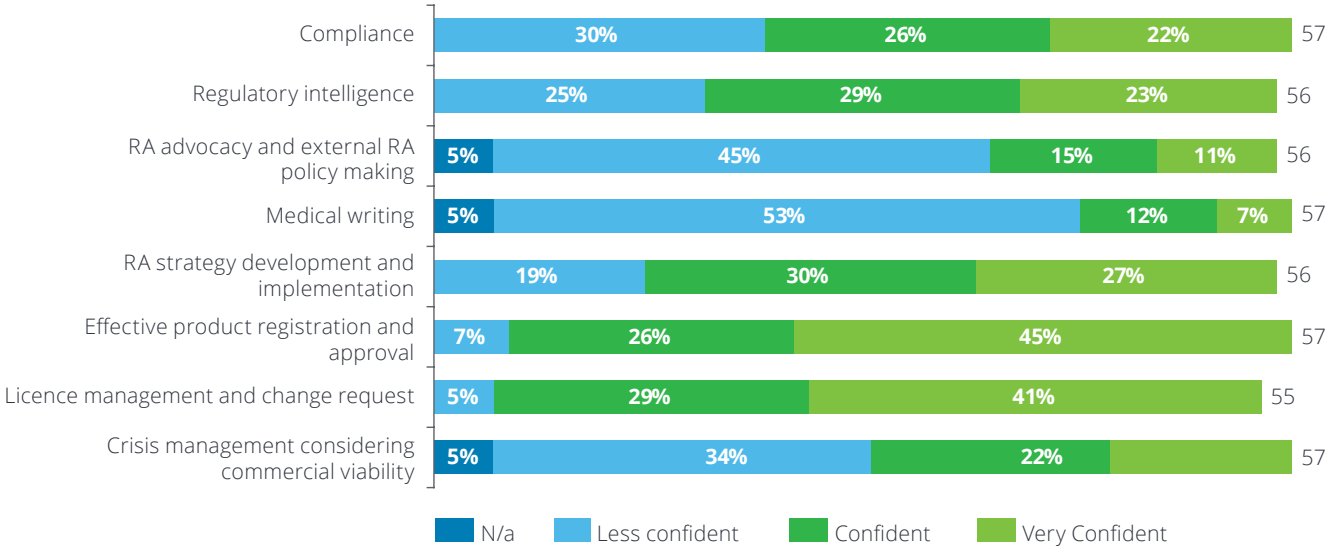
RA function's current confidence in scope of activities



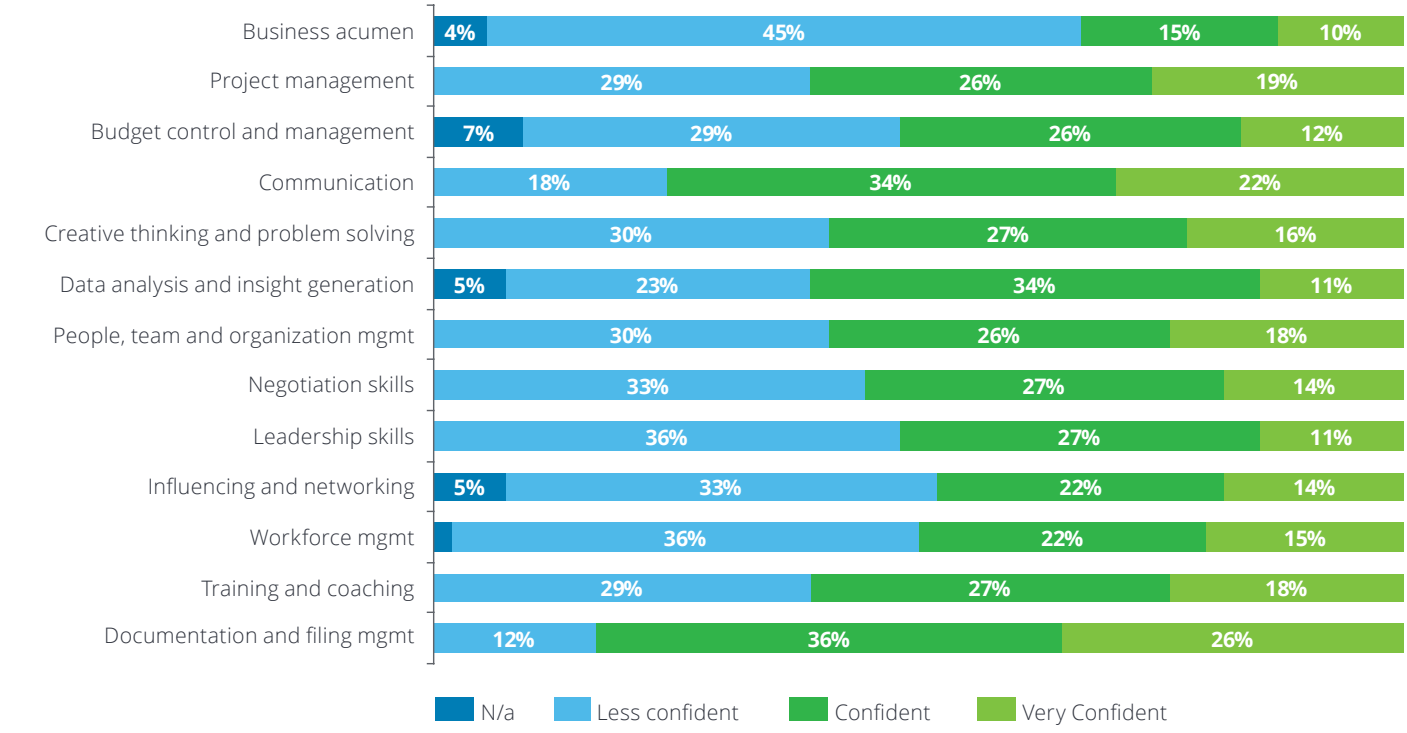
- **46%** RA professionals feel they are not confident working with regulators and shaping the regulatory landscape
- **81%** stakeholders perceived RA operations activities are among the best work of RA
- Although considered important but **46%** stakeholders noted RA stakeholder management as one of the worst processes managed by RA today

- From a functional view, **medical writing, RA advocacy and crisis management** are seen as areas where RA professionals need to up-skill. In terms of foundational competencies, **business acumen** is identified as priority skill that needsfor development, followed by **leadership, workforce management and negotiation skill.**

RA function – Functional Competency



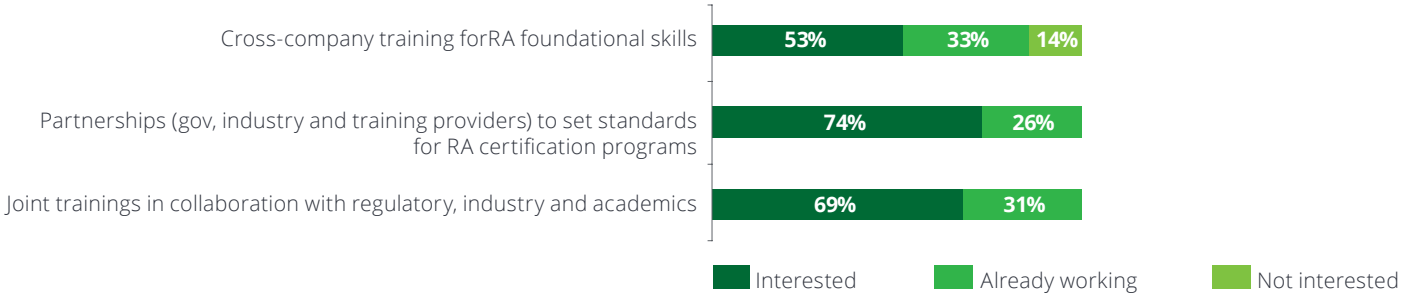
RA function – Foundational Competency



- **53%** RA professionals are not confident in medical writing and **45%** are not confident in RA advocacy
- **45%** RA professionals are not confident in business acumen or lacking sense of business purpose

- The challenges in RA performance and competency gaps are fundamental and require industry players to look at ways of complementing their talent pool with new assets and capabilities - internally and through collaborative efforts. Three potential MedTech initiatives were identified: **cross-company training** within the industry, **partnerships to set RA certification programs** standards and **joint trainings** in collaboration with regulator, industry and academics.

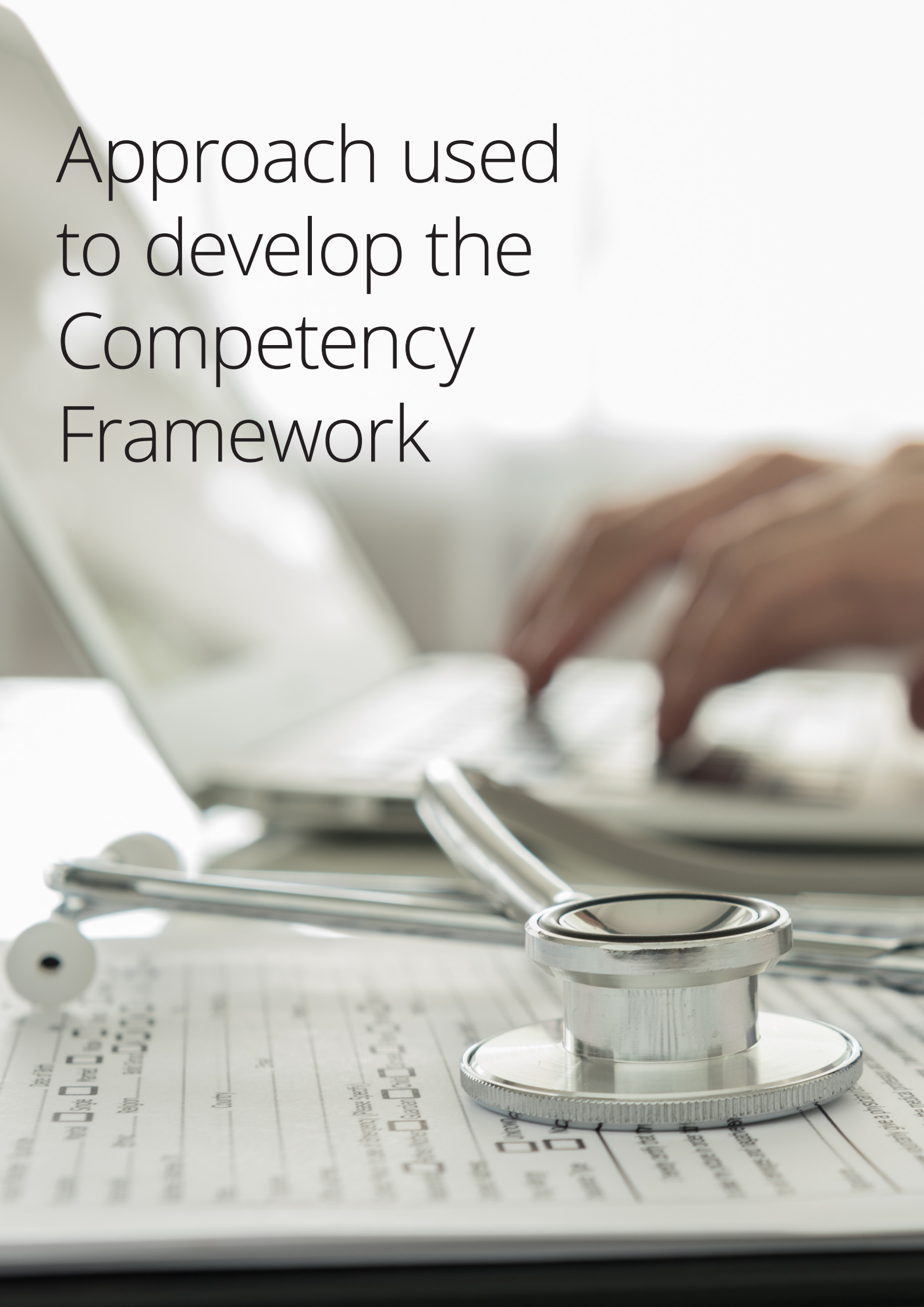
Initiatives to drive RA capacity building



- **74%** respondents are interested in industry partnership of RA certification program standards and 26% have been working towards it
- **69%** respondents are interested in industry-regulatory joint trainings and **31%** are working on it

This white paper aims to address the above complexities and industry challenges by introducing a competency framework for RA professionals.

Approach used to develop the Competency Framework



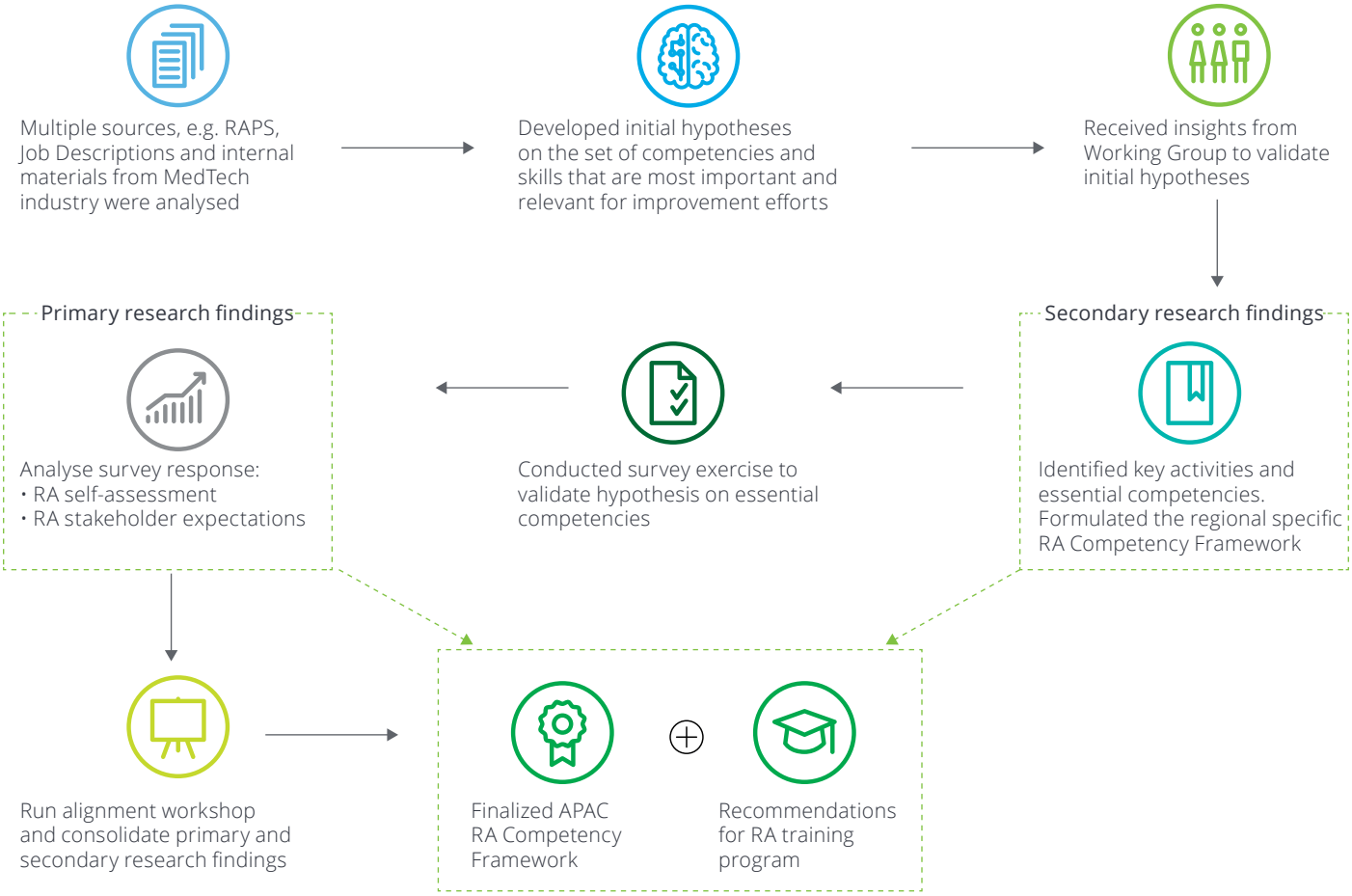
This whitepaper uses insights from Primary and Secondary research to validate initial hypotheses on essential competencies expected of RA professionals in the APAC region.

Findings from Secondary research helped highlight key activities and competencies that are essential for RA professionals. In order to enhance and 'localize' the focus of this study further, the approach integrated a regional perspective into the RA Competency Framework by using, the Regulatory Affairs Professionals Society's (RAPS) Professional Development Framework (PD Framework) as a guideline, and incorporated insights from MedTech companies within the APAC region.

Primary research was targeted at gathering expectation of RA's activities and competencies from both the RA's as well as business users of the RA function in the MedTech companies. The two surveys considered the challenges faced by MedTech RA's through a self-assessment of 67 RA individuals, as well as the expectations of 63 cross-functional stakeholders[2].

In summary, survey results indicate a substantial gap in and strong demand for capability improvements of MedTech RA professionals.

Competency Framework Development Approach



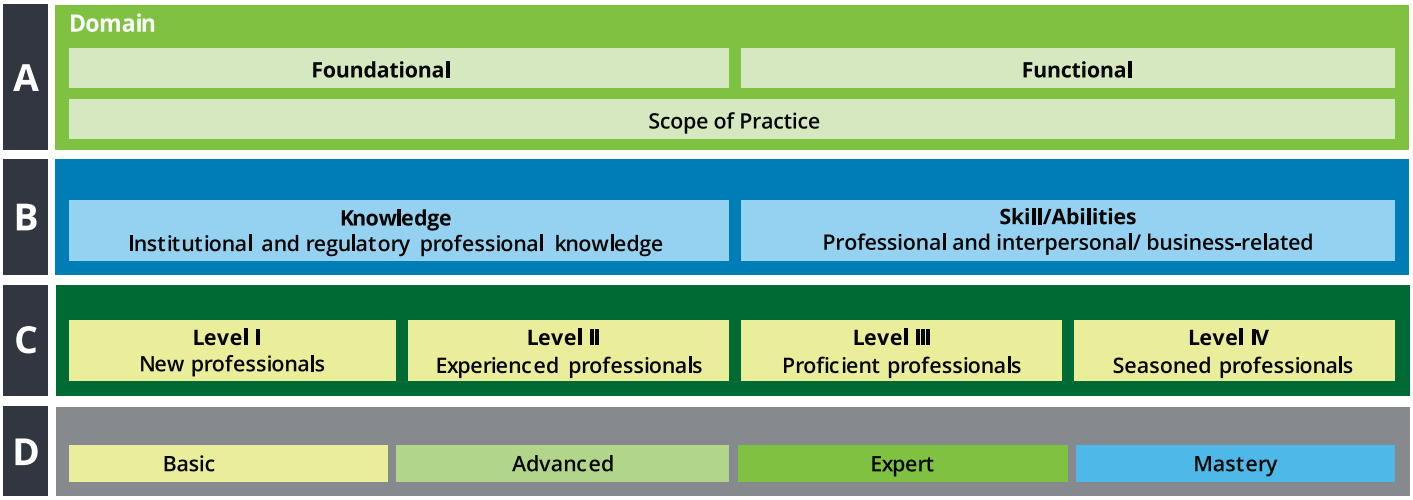
[2] Individuals primarily from commercials, supply chain and medical affair functions

APAC RA Competency Framework

This Competency Framework is designed based on four elements:

1) **Domains,** which reflects scope of responsibilities throughout the product lifecycle
2) **Competency,** which documents the essential skills in each domain across Knowledge, Skills and Abilities
3) **Professional Levels,** refer to one of four professional/ career levels, and
4) **Proficiency Levels,** represent the required ability of an individual to perform specific competency at a certain professional level

RA Competency High Level Framework



A. Domain and Scope of Practice

Domain

Domains represent the major content categories within each level of the Framework. The two domains, Foundational and Functional, are constructed to include typical activities and responsibilities of RA professionals throughout all stages of the product lifecycle.

Foundational domain emphasizes the overarching roles and activities required by MedTech industry professionals as a whole. This domain includes the following area:

- Business Operation
- Communication
- Project Management
- People Management
- Business Strategy
- Business Partnering

Functional domain emphasizes day-to-day roles and functions throughout the product lifecycle in each company. It includes the following area:

- Regulatory Knowledge and Application
- Regulatory Strategy
- Pre-Marketing
- Post-Marketing
- Quality / Compliance

Interfacing takes into account responsibilities that encompass both internal and external communication and interaction (i.e. within the organization, with all other cross-functional stakeholders and regulatory agencies).

Scope of Practice

The scope of practice is the first step to building effective regulatory capacity in the region. It represents the work being carried out by professionals from both the industry and regulatory spectrums. As a foundation for defining the competencies, it also serves as a guide for education and training curriculums for continued professional development. Following the domains, scope of practice is also mapped to Functional and Foundational activities for MedTech industry professionals.

Scope of Practice — Covers the scope and range of responsibilities and key activities which regulatory professional shall perform as part of their role and function in the MedTech industry

Functional

Product Development

- Advise regulatory requirement for pre-clinical research and data
- Assess the acceptability of quality and pre-clinical documentation for submission filing

Clinical Investigation

- Advise regulatory requirements for clinical studies
- Assess the acceptability of clinical documentation for submission filing

Product Registration

- Submission requirement and process
- Compile and organize materials for preparation of submission package
- Negotiate with regulatory authorities
- Monitor applications under regulatory review

Post-Marketing

- Maintain license and registration status
- Vigilance reporting
- Ensure post-marketing compliance
- Monitor product safety and adverse event
- Support change control activities
- Crisis management

Quality & Compliance

- Review international and local quality system requirement
- Promote ethics and compliance culture

Regulatory Concept & Application

- Apply and comply with global and local regulation, guidelines and standards during all phases of product development and commercialization

Regulatory Strategy

- Perform regulatory intelligence and provide inputs for regulatory strategy and product development
- Develop optimal submission strategy
- Advocate and shape regulatory landscape

Foundational

Business Operation

- Deliver business partner activities
- Address business queries and solve problems
- Partake in business operation standard setting
- Perform budget control and management

Business Strategy

- Support business strategy by providing strategic regulatory inputs and technical guidance

Communication

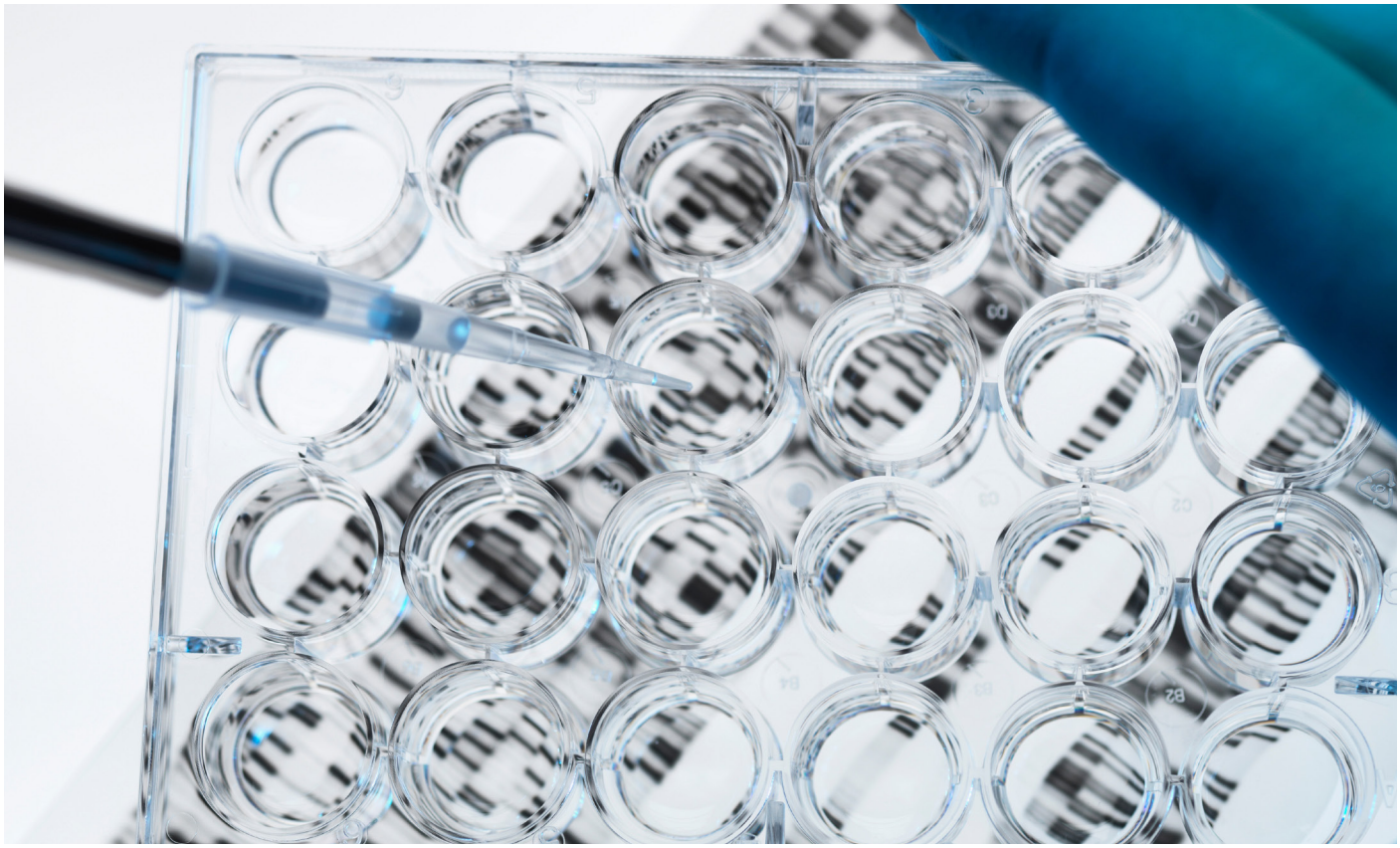
- Communicate effectively and clearly (verbal and written) on RA topics and technical information
- Communicate with internal stakeholders
- Strategic negotiation with regulatory authorities and other external customers

Project Management

- Plan, execute and manage project (incl. scope, resource, budget, cost, timeline and outcome)
- Sole project related problems and issues
- Manage project stakeholders
- Perform quality and risk management

People Management

- Manage and maintain relationship with internal and external stakeholders
- Build capability, motivate, coach and mentor RA staff
- Plan RA workforce
- Conduct performance appraisals



B. Competencies

Summarized as the amalgamation of experience, skills, abilities, and personal attributes that drive and enhance the performance of each RA professional, the framework details the competencies for each domain (Functional and Foundational) that are paramount to a MedTech organizations' success. Key competencies and detailed interpretation of each of these domains are stipulated in the Appendix - *Identified Competencies.*

Domain and Competency

Domain — **Domain is structured into two, Foundational and Functional, and represents major and sub-areas describing the key roles, responsibilities and tasks to be delivered**

Foundational		Functional	
• Business Operation	• People Management	• Regulatory Knowledge and Application	• Pre-Marketing
• Communication	• Business Strategy	• Regulatory Strategy	• Post-Marketing
• Project Management	• Business Partnering		• Quality / Compliance

Essential Competencies — **Are defined as the combination of knowledge, skills, abilities and personal attributes that to drive and enhance the employee's performance and lead to the organization's success. There are types of competencies, one those related to the profession (functional) and second, those required cross-functionally (foundational).**

Professional Level

Knowledge — **Institutional and regulatory professional knowledge**

Skill/Abilities — **Professional and interpersonal/ business-related**

Level I	Level II	Level III	Level IV
Professionals new in the function with limited or no regulatory affairs knowledge. Typical educational backgrounds are in science, clinical studies or engineering with understanding of the healthcare product scope	More experienced functional professional with strong emphasis on technical aspects, combined with scientific understanding and project management with more active involvement in conceptualizing the company's RA strategy	Professionals who integrate regulatory knowledge throughout the product lifecycle and proficient and are effective in management their part of the RA function and contribute to strategy development	Seasoned RA professionals who lead strategic activities of the function and develop developing new and innovative approaches to support the business. Their focus is on strategic planning, stakeholder management and government relations

Proficiency Level

Basic	Advanced	Expert	Mastery
Common knowledge or an understanding of basic techniques and concepts	More comprehensive and technical knowledge of the particular task or skill and self-sufficient to perform assigned tasks independently	Deep and comprehensive knowledge of the particular task or skill and sufficient expert to deliver assignments and to adapt to changing environments and demands	Full expertise of the particular task or skill together with high proficiency and specialised skills to run RA function and complex projects

C. Professional Levels

Professional Level refers to one of four professional/ career levels based on level of experience and maturity in performing RA responsibilities and activities.

Level 1
Professionals from Level 1 are typically new to regulatory affairs. Many have scientific, clinical or engineering backgrounds and understand specific aspects of the healthcare product arena. These professionals should possess project management, writing, interpersonal and communication skills, among others.

Level 2
Professionals that develop an understanding of regulatory affairs throughout the product lifecycle. There is a strong emphasis on technical aspects of the profession, scientific understanding and project management. These professionals often expand their involvement with international/ multinational regulatory perspectives and begin more active involvement with regulatory strategy.

Level 3
Level 3 professionals integrate regulatory knowledge throughout the product lifecycle with aspects of effective management and strategy development. This level represents the move from the technical and tactical dimensions of RA and the product lifecycle into a more strategic role.

Level 4
These professionals assume the strategic lead representing the regulatory perspective while developing new approaches for business objectives. Strategic planning and interfacing throughout the product lifecycle, both within and external to the organization, are among the most important responsibilities. These professionals must be able to work effectively in multinational/multicultural environments.

D. Competency and Proficiency Map

Based on the above framework, a Resulting Competency and Proficiency Map that is relevant to RA professionals in the MedTech industry was developed. By mapping these essential competencies against Professional Levels and Domains, companies will be able to identify the required proficiency of these competencies that are expected at each of these levels.

Both Foundational and Functional Competency Maps show that all domains require a proficiency of Mastery at Level 4, and a mixture of Expert and Mastery Proficiency levels at Level 3. When considering level 1, most Domains require a Basic Proficiency and Level 2 requires mostly Advanced proficiency levels with some Basic and Expert levels too.

Foundational Resulting Competencies and Proficiency Map

Foundational Domain	Knowledge / Ability	Proficiency Level			
		Level 1	Level 2	Level 3	Level 4
Business Operation	Strong business acumen/ Commercial awareness	Basic	Advanced	Mastery	Mastery
	Knowledge on products, processes, and business units	Advanced	Expert	Mastery	Mastery
	Knowledge and understanding of regulatory interacts with other functions to achieve business objectives	Basic	Advanced	Expert	Mastery
	Creative skills: flexibility (ability to produce a varied mix of ideas); elaboration (ability to add detail, depth, mixtures of viewpoints or perspectives); and originality, uniqueness, novelty, or innovativeness	Basic	Advanced	Expert	Mastery
	Understand corporate finance requirements and models	N/A	Basic	Expert	Mastery
	Plan and manage budgets that are in line with business requirements for growth	N/A	Basic	Expert	Mastery
	Be able to develop regulatory relevant business cases	N/A	Basic	Expert	Mastery
Communication (verbal and written)	Effective communication on complex regulatory topics	Basic	Advanced	Expert	Mastery
	Tailor communication style to listener's perspective to guide, influence, and convince stakeholders	Basic	Advanced	Mastery	Mastery
	Conduct strategic negotiation with regulatory authorities	N/A	Basic	Expert	Mastery
	Medical writing	Advanced	Advanced	Expert	Mastery
Project Management	Plan, execute and manage project (incl. scope, resource, budget, cost, timeline and outcome)	Basic	Advanced	Expert	Mastery
	Problem solving skills	Advanced	Expert	Expert	Mastery
	Interpersonal skills	Basic	Advanced	Expert	Mastery
	Project quality and risk management	N/A	Basic	Expert	Mastery
People Management	Lead, motivate, and deliver training to regulatory and other functions	N/A	N/A	Expert	Mastery
	Contribute to workforce planning (incl. hiring, development, succession planning) and performance assessment	N/A	N/A	Expert	Mastery
	Develop and maintain relationships with internal and external stakeholders	N/A	Basic	Expert	Mastery
	Leadership		Advanced	Expert	Mastery

Foundational Resulting Competencies and Proficiency Map (Cont'd)

Foundational Domain	Knowledge / Ability	Proficiency Level			
		Level 1	Level 2	Level 3	Level 4
Business Strategy	Understand regulatory requirements applied throughout the lifecycle to bridge business and clinical objectives with regulatory requirements	Basic	Advanced	Expert	Mastery
	Analyse regulatory guidelines, policies and actions to determine regulatory and legal impact on the company	Basic	Advanced	Mastery	Mastery
	Strategic thinking, business processes, project management	N/A	Basic	Expert	Mastery

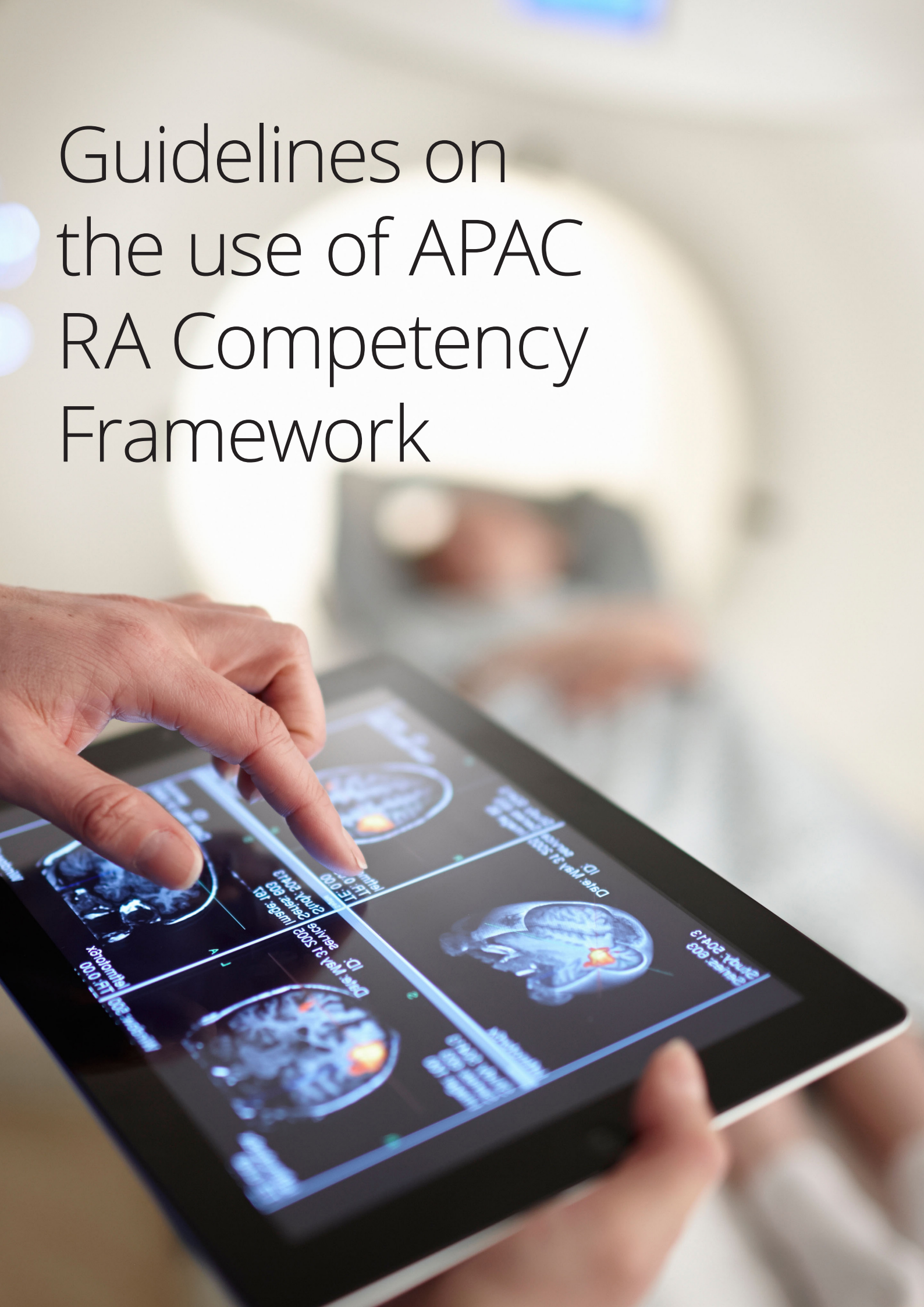
Functional Resulting Competencies and Proficiency Map

Functional Domain	Knowledge / Ability	Proficiency Level			
		Level 1	Level 2	Level 3	Level 4
Regulatory Knowledge and Application	Knowledge of laws, guidelines, procedures and concepts within Regulatory Affairs	Basic	Advanced	Mastery	Mastery
	Ability to apply and implement the correct domestic and international laws, regulations, guidelines, standards, ethics, and procedures to obtain regulatory approval	Basic	Advanced	Mastery	Mastery
	Knowledge of and complies with corporate internal policies and procedures	Basic	Advanced	Mastery	Mastery
Regulatory Strategy	Provide regulatory intelligence for regulatory strategy & product development (incl. data processing, competitor analysis, environmental intelligence, due diligence support)	Basic	Advanced	Expert	Mastery
	Develop optimal submission strategy and plans	N/A	Basic	Expert	Mastery
	Able to assess business impact with a given regulatory strategy	N/A	Basic	Expert	Mastery
	Impact and influence downstream decisions pertaining to testing, labelling, and clinical requirements	N/A	Basic	Expert	Mastery
	Advocate for and shape regulatory landscape	N/A	Basic		
Premarketing	Provide strategic inputs and regulatory guidance for premarket approval	Basic	Advanced	Expert	Mastery
	Review acceptability of quality, preclinical and clinical documentation and data, statistical methods and analysis	Basic	Advanced	Expert	Mastery
	Prepare and compile regulatory submission packages	Basic	Advanced	Mastery	Mastery
	Negotiate with regulatory authorities and perform other regulatory intervention	N/A	Basic	Expert	Mastery
	Understanding of statistics, data analysis	Basic	Advanced	Expert	Mastery
Post-marketing	Maintain databases and repositories of license and registration documents	Advanced	Expert	Mastery	Mastery
	Deal with the regulatory aspects of advertising, labelling and promotional materials	Basic	Advanced	Expert	Mastery
	Submit and review change controls to determine the level of change and consequent submission requirements	Basic	Advanced	Mastery	Mastery
	Review and approve required reports, supplemental submissions to update and maintain product approvals and registrations	N/A	Advanced	Mastery	Mastery
	Manage product safety and report adverse events to regulatory agencies and internal stakeholders	N/A	Advanced	Expert	Mastery
	Crisis management	N/A	Basic	Expert	Mastery

Functional Resulting Competencies and Proficiency Map (Cont'd)

Functional Domain	Knowledge / Ability	Proficiency Level			
		Level 1	Level 2	Level 3	Level 4
Quality/ Compliance	Promote ethics and create compliance culture	N/A	Basic	Expert	Mastery
	Provide regulatory support during internal and external audits	Basic	Advanced	Expert	Mastery
	Implement quality standards, design control, process control, supplier qualification	N/A	Basic	Expert	Mastery
	Risk assessment	Advanced	Expert	Mastery	Mastery

Guidelines on the use of APAC RA Competency Framework



The growing gap between market demands and the required competencies of RA professionals reiterates the need to invest in the professions capacity building in APAC. This framework provides a detailed description of the competencies and skillset required from RA professionals. Outlining the responsibilities, knowledge and skills of professionals at the various stages of development, the framework offers a tool for career development planning by the individual professional, the regulatory manager and mentor, and by organizations. However, given its foundational and generic nature, organizations and individuals should use it as a basis, and refine and its content to be relevant to the individual and/or organization in question.

Essential to the success of this process is the effective collaboration between the RA professionals and industry regulators. The APAC RA Competency Framework can be used as a guideline to initiate discussions and collaborative efforts between the two.

This framework was also designed to serve as a stimulant for dialogue and discussion between RA professionals and regulatory bodies in APAC with an intent to address RA function's challenges and deliver greater and safer access to MedTech innovation in the region.

Using the Framework

1 Foundational domain	2 Knowledge / Ability	3 Proficiency Level			
		Level 1	Level 2	Level 3	Level 4
Business Partnering	Strong business acumen/ Commercial awareness	Basic	Advanced	Mastery	Mastery
	Knowledge on products, processes, and business units	Advanced	Expert	Mastery	Mastery
	Knowledge and understanding of regulatory interacts with other functions to achieve business objectives	Basic	Advanced	Expert	Mastery
	Creative skills: flexibility (ability to produce a varied mix of ideas); elaboration (ability to add detail, depth, mixtures of viewpoints or perspectives); and originality, uniqueness, novelty, or innovativeness	Basic	Advanced	Expert	Mastery
Communication (verbal and written)	Effective communication on complex regulatory topics	Basic	Advanced	Expert	Mastery
	Tailor communication style to listener's perspective to guide, influence, and convince stakeholders	Basic	Advanced	Mastery	Mastery
	Conduct strategic negotiation with regulatory authorities	N/A	Basic	Expert	Mastery
	Medical writing	Advanced	Advanced	Expert	Mastery

An organization can use the framework as reference of RA competency mapping by defining each element of the framework, which includes:

1. **Domain** - major and sub-areas describing the key roles, responsibilities and tasks to be delivered (e.g. Business Partnering, Communication, People Management, etc.)
2. **Competencies** - knowledge, skills, abilities and personal attributes that drive employee's performance and lead to the organization's success (e.g. Business acumen, knowledge on product, etc.)
3. **Professional Level** - one of four professional/ career levels (e.g. Level 1-4 based on level of experience and maturity)
4. **Proficiency Level** - required ability of an individual to perform specific competency (e.g. Basic/Advanced/Expert/Mastery)

1 Domain
Domains represent the major and sub-areas describing the key roles, responsibilities and tasks to be delivered

2 Competencies
Combination of knowledge, skills, abilities and personal attributes to drive employee's performance and lead to the organization's success

3 Professional Level
This element refers to one of four professional/ career levels

4 Proficiency Level
Proficiency level represents the required ability of an individual to perform specific competency

Appendices

Identified Competencies

Foundational

Business Partnering	Strong business acumen/ Commercial awareness	Knowledge on products, processes, and business units	Knowledge and understanding of regulatory interacts with other functions to achieve business objectives	Creative skills: flexibility, and originality, uniqueness, novelty, or innovativeness
Communication	Effective communication on complex regulatory topics	Tailor communication style to listener's perspective to guide, influence, and convince stakeholders	Conduct strategic negotiation with regulatory authorities	Medical writing
People Management	Lead, motivate, and deliver training to regulatory and other functions	Contribute to workforce planning (incl. hiring, development, succession planning) and performance assessment	Develop and maintain relationships with internal and external stakeholders	Leadership skills
Project Management	Plan, execute and manage project (scope, resource, budget, cost, timeline, outcome)	Problem solving skills	Interpersonal skills	Project quality and risk management
Business Strategy	Understand regulatory requirements applied throughout the lifecycle to bridge business and clinical objectives with regulatory requirements	Analyse regulatory guidelines, policies and actions to determine regulatory and legal impact on the company	Strategic thinking. business processes, project management	
Finance	Understand corporate finance requirements and models	Plan and manage budgets that are in line with business requirements for growth	Be able to develop regulatory relevant business cases	

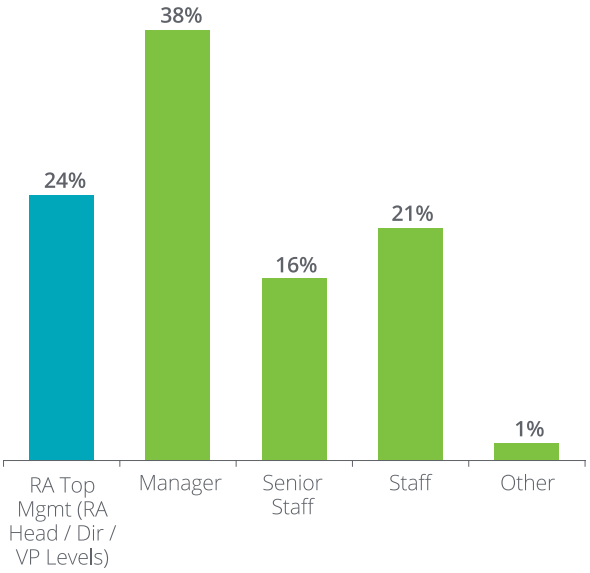
Functional

Regulatory Knowledge and Application	Knowledge of laws, guidelines, procedures and concepts within Regulatory Affairs	Ability to apply and implement the correct domestic and international laws, regulations, guidelines, standards, ethics, and procedures to obtain regulatory approval	Knowledge of and complies with corporate internal policies and procedures	
Regulatory Strategy	Provide regulatory intelligence for regulatory strategy & product	Develop optimal submission strategy and plans	Impact and influence downstream decisions pertaining to testing, labelling, and clinical requirements	Advocate for and shape regulatory landscape
Premarketing	Provide strategic inputs and regulatory guidance for premarket approval	Review acceptability of quality, preclinical and clinical documentation and data, statistical methods and analysis	Prepare and compile regulatory submission packages	Review and approve required reports, supplemental submissions to update and maintain product approvals and registrations
	Understanding of statistics, data analysis			
Postmarketing	Maintain databases and repositories of license and registration documents	Deal with the regulatory aspects of advertising, labelling and promotional materials	Submit and review change controls to determine the level of change and consequent submission requirements	
	Manage product safety and report adverse events to regulatory agencies and internal stakeholders	Crisis management		
Quality/Compliance	Promote ethics and create compliance culture	Provide regulatory support during internal and external audits	Implement quality standards, design control, process control, supplier qualification	Risk assessment

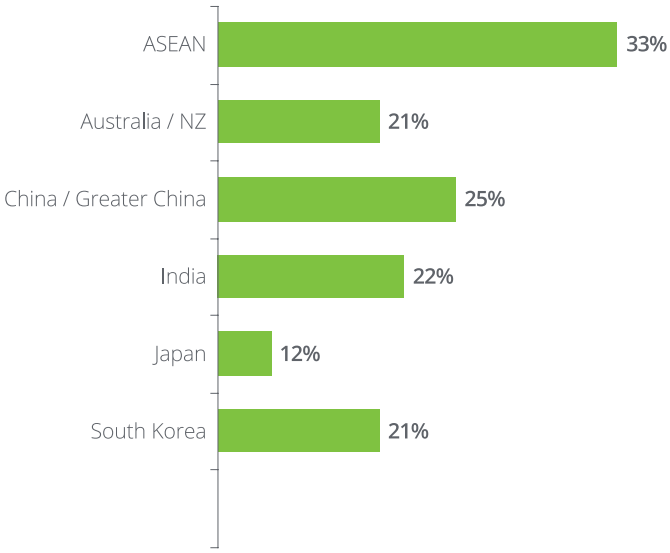
Survey to RA Professionals and Stakeholders

RA Survey Statistics – 67 respondents

Functions

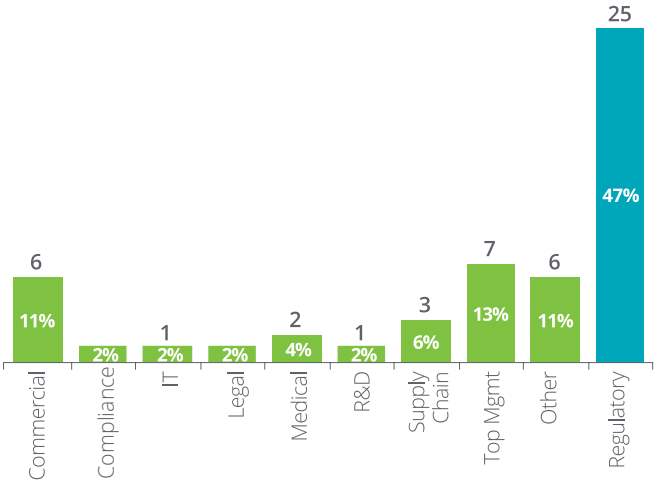


Scope of responsibility

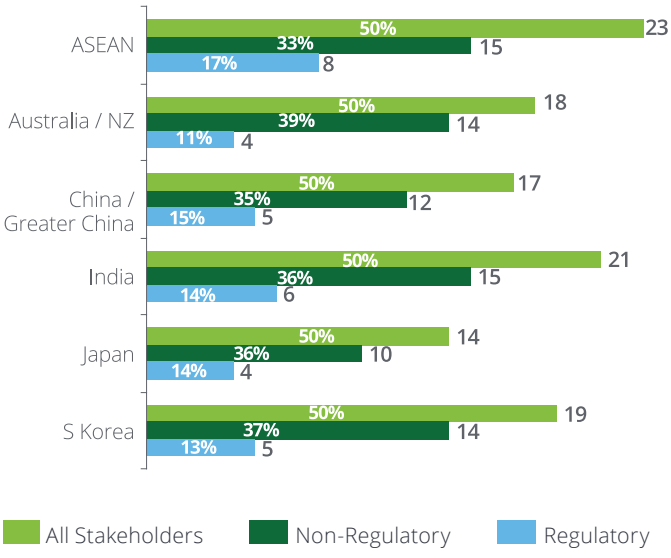


Stakeholder Survey – 63 respondents

Functions



Scope of responsibility



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

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Steering Committee and Working Group Members

Quan Tran
Vice President Regulatory Affairs
Asia Pacific Medical Technology Association (APACMed)

Miang Tanakasemsub
APACMed RA Co-Chair
Regional Regulatory Affairs Head, Asia Pacific & Russia
Alcon

Jason Guo
APACMed RA Co-Chair
Director, Regulatory Affairs & Quality Compliance, Asia Pacific
Abbott Vascular

Jack Wong
Head of RA, APAC
Baxter International Inc.

Wing Gang Seet
Head of Regulatory Intelligence, Greater Asia
Becton Dickinson

Ee Lin Thum
Associate Manager, Regulatory Affairs, APAC
Biosensors

Dominik Reterski
Vice President Quality and Regulatory Affairs Asia Pacific
Medtronic

Schneider Adelheid
Regulatory Affairs and Quality
Roche Diagnostic Asia Pacific

Contacts

APACMed

Quan Tran
Vice President Regulatory Affairs
Asia Pacific Medical Technology Association (APACMed)

Miang Tanakasemsub
APACMed RA Co-Chair
Regional Regulatory Affairs Head, Asia Pacific & Russia
Alcon

Jason Guo
APACMed RA Vice Chair
Director, Regulatory Affairs & Quality Compliance, Asia Pacific
Abbott Vascular

info@apacmed.org
www.apacmed.org

Deloitte Southeast Asia

Sachin Shah
Executive Director
Deloitte Consulting SEA

Debmalya Chatterjee
Director
Deloitte Consulting SEA

Liu Dan
Senior Consultant
Deloitte Consulting SEA

SGDCLifeSciences@DELOITTE.com
www2.deloitte.com/sg