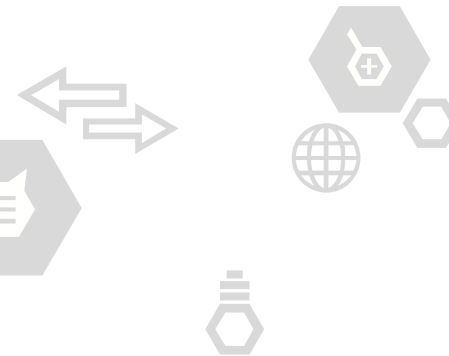




Competency Framework for Asia Pacific MedTech Regulatory Professionals

10 Jan 2018



Agenda

- **Background Introduction**
- **Study Approach**
- **Competency Framework for MedTech RA professionals in APAC**
- **Q&A at the end of the session**

Presenter



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Debmalya is a Director in Deloitte Consulting's Life Sciences practice based out of the Singapore office. Debmalya brings over 15 years of experience across US, Europe and APAC and specializes in supply chain and manufacturing operations, more specifically in the areas of operations efficiency improvement, working capital optimization, supply chain planning and execution.

Prior to consulting, Debmalya worked with J&J Medical in US and India leading Franchise Supply Chain and Commercial Operations.

Debmalya holds an MBA from Kellogg School of Management, Northwestern University and is a APICS certified professional



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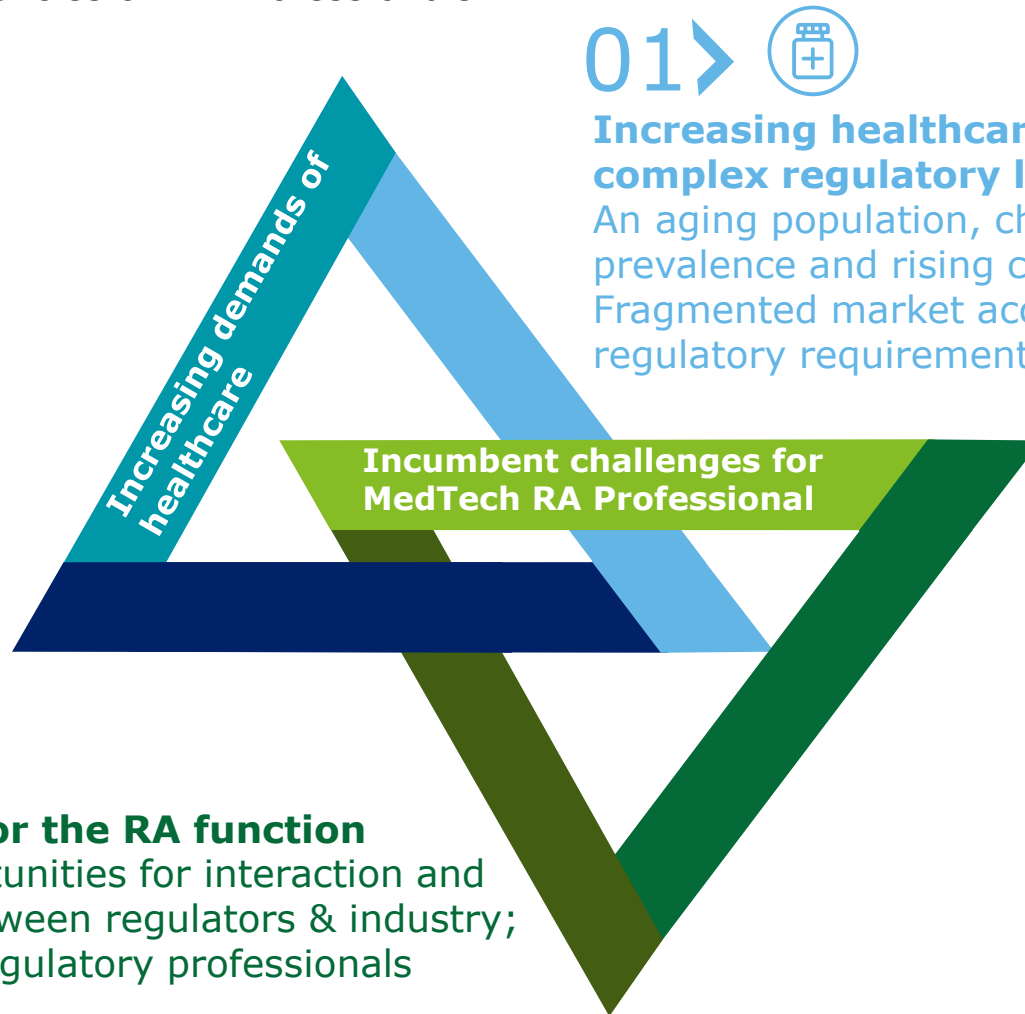
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Dan is a Senior Consultant in Deloitte Consulting's Life Sciences practice. Dan has over eight years of experience across consulting and research experience in Life Sciences and Healthcare sector. She has worked with global Pharma and MedTech clients on several areas such as operating model transformation, pre-M&A business due diligence, business model innovation, commercial excellence and regulatory affairs.

Prior to joining Deloitte, Dan has earned a Ph.D in Cancer Biology with a profound knowledge in understanding pharma products and biotechnologies.

Background and imperative need for MedTech regulatory capability building

Increasing demands of healthcare coupled with inherent challenges of RA* function drive a need to define and standardize essential competencies of RA Professionals



01 > 

Increasing healthcare demand and complex regulatory landscape

An aging population, chronic disease prevalence and rising cost of healthcare; Fragmented market access and diverse regulatory requirement

02 > 

Challenges for the RA function

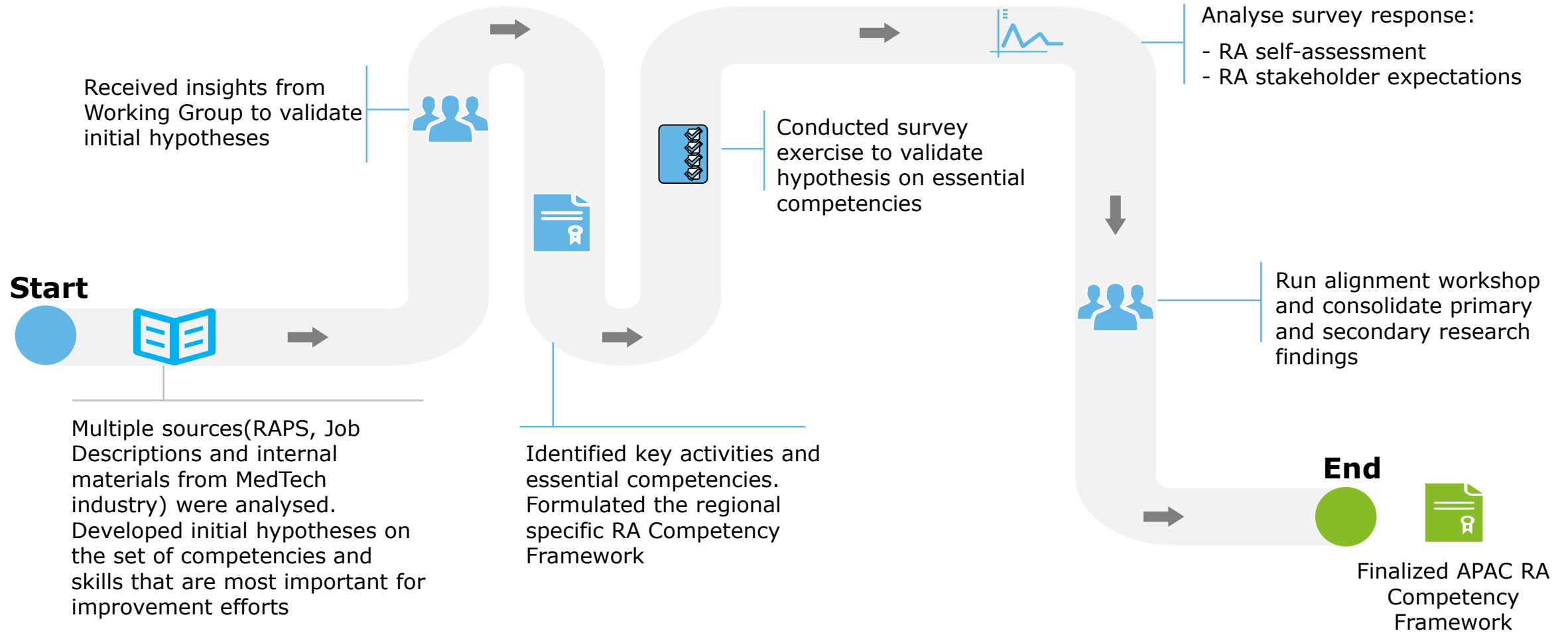
Limited opportunities for interaction and discussion between regulators & industry; Shortage of regulatory professionals

03 > 

In order to solve this dilemma, 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

* Regulatory Affairs

Approach used to develop RA Competency Framework...



Two surveys were conducted to define future direction of regulatory training and development

What?

Uncover common RA internal priorities, challenges and focus areas for capability building

Who?

RA professionals from MedTech industry

Respondents: 67



What?

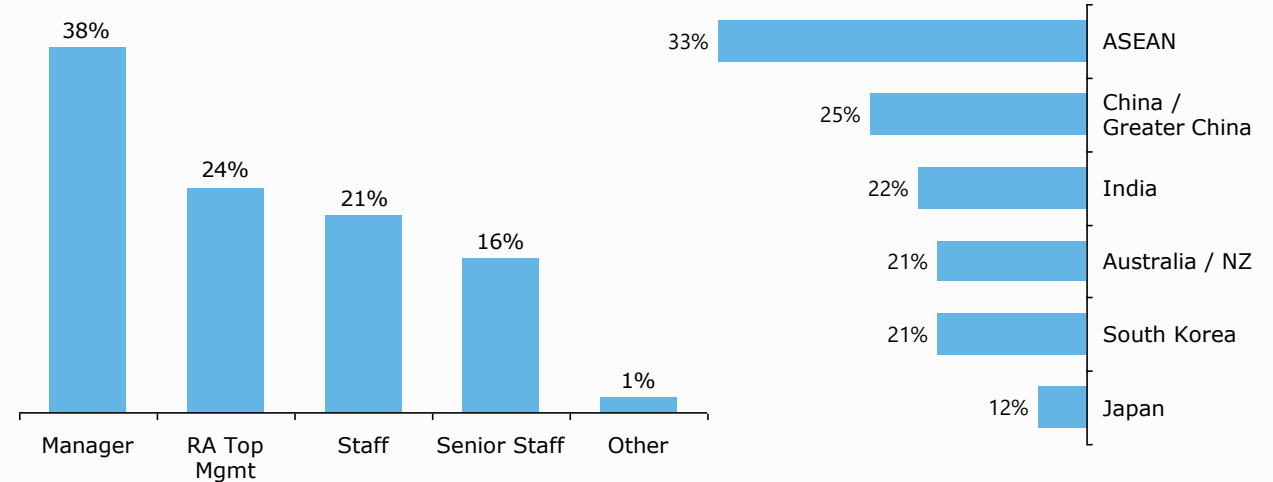
Explore cross-functional stakeholder expectation for RA professionals

Who?

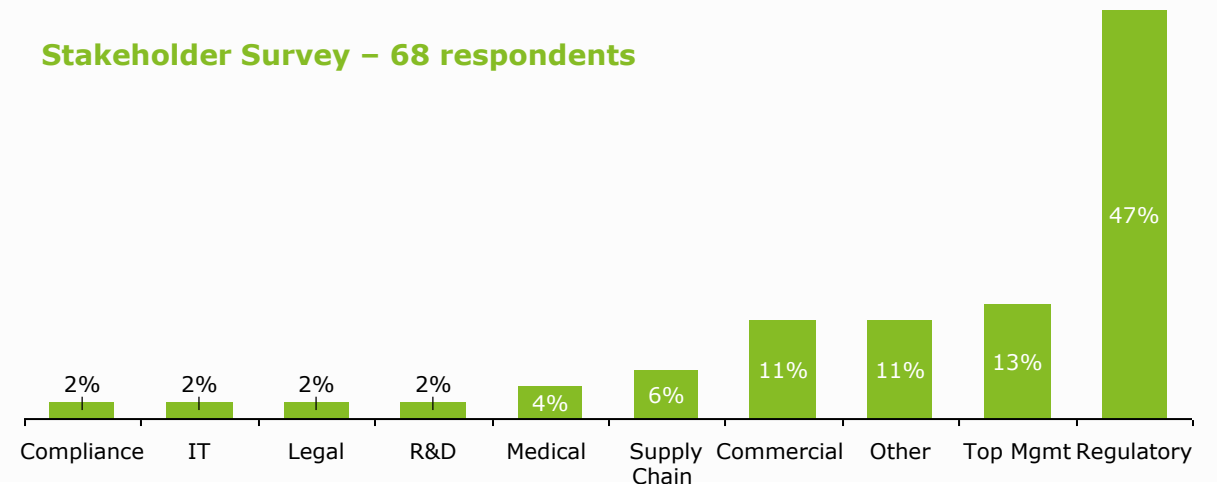
Cross-functional stakeholders from MedTech industry

Respondents: 68

RA Survey Statistics – 67 respondents



Stakeholder Survey – 68 respondents



Highlights of the survey results

Key Survey Insights

1

RA Self Evaluation: Confident in performing most of the RA activities; **Medical writing, RA advocacy and crisis management** are seen as **potential areas of improvement**

2

Stakeholder Evaluation: **Stakeholder management** and **Business partnering** need significant improvement

3

Business acumen is identified as a priority skill **needed for development**, followed by **leadership, workforce management and negotiation skill**

4

Industry players are required to look at ways of complementing their talent pool with new assets and capabilities through collaborative efforts - **cross-company training, partnerships to set RA certification programs standards** and **joint trainings in collaboration with regulator, industry and academics**

Introduction to MedTech RA professional competency framework

This Competency Framework is designed based on four elements:

Domain

Covers **responsibilities and activities** of RA professionals throughout all stages of the product lifecycle.

Competency

Lists the **knowledge, skills/abilities** required to perform all the activities identified in the domains.

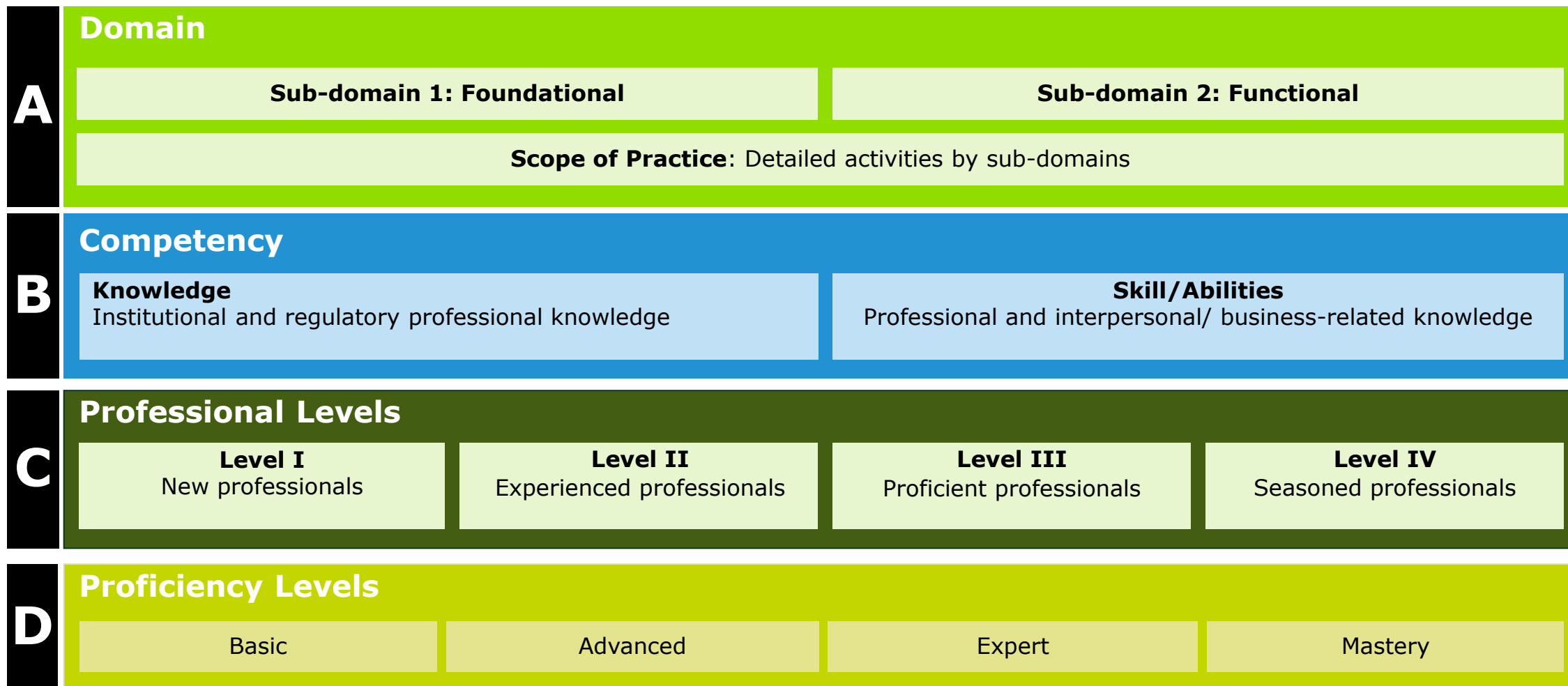
Professional Levels

Refers to one of four professional/ career levels defined by **years of experience**

Proficiency Levels

Represent the **required ability** of a RA individual across competencies and professional level

RA competency high-level framework



A- Domain



Domain

Covers **responsibilities and activities** of RA professionals throughout all stages of the product lifecycle.



Competency

Reflects the knowledge, skills/abilities required to perform all the activities identified in the domains.



Professional Levels

Refer to one of four professional/career levels



Proficiency Levels

Represent the required ability of an individual to perform specific competency at a certain professional level

A- Domain

A	Domain	
	Sub-domain 1: Functional	Sub-domain 2: Foundational
	Scope of Practice: Detailed activities by sub-domains	

A- Domain

A

Domain

Sub-domain 1: Functional

Sub-domain 2: Foundational

Scope of Practice: Detailed activities by sub-domains

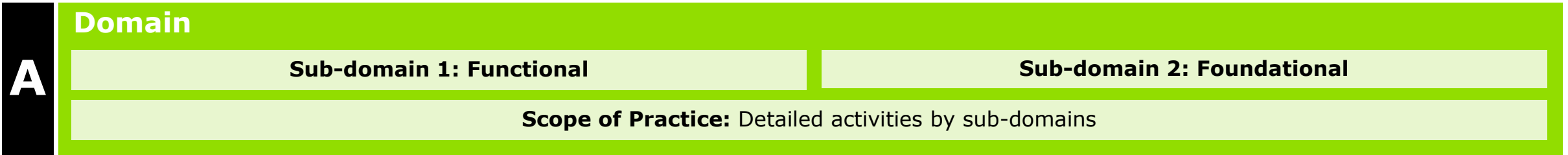
Functional

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

Foundational

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

A- Domain



Scope of Practice

Regulatory activities by product life cycle



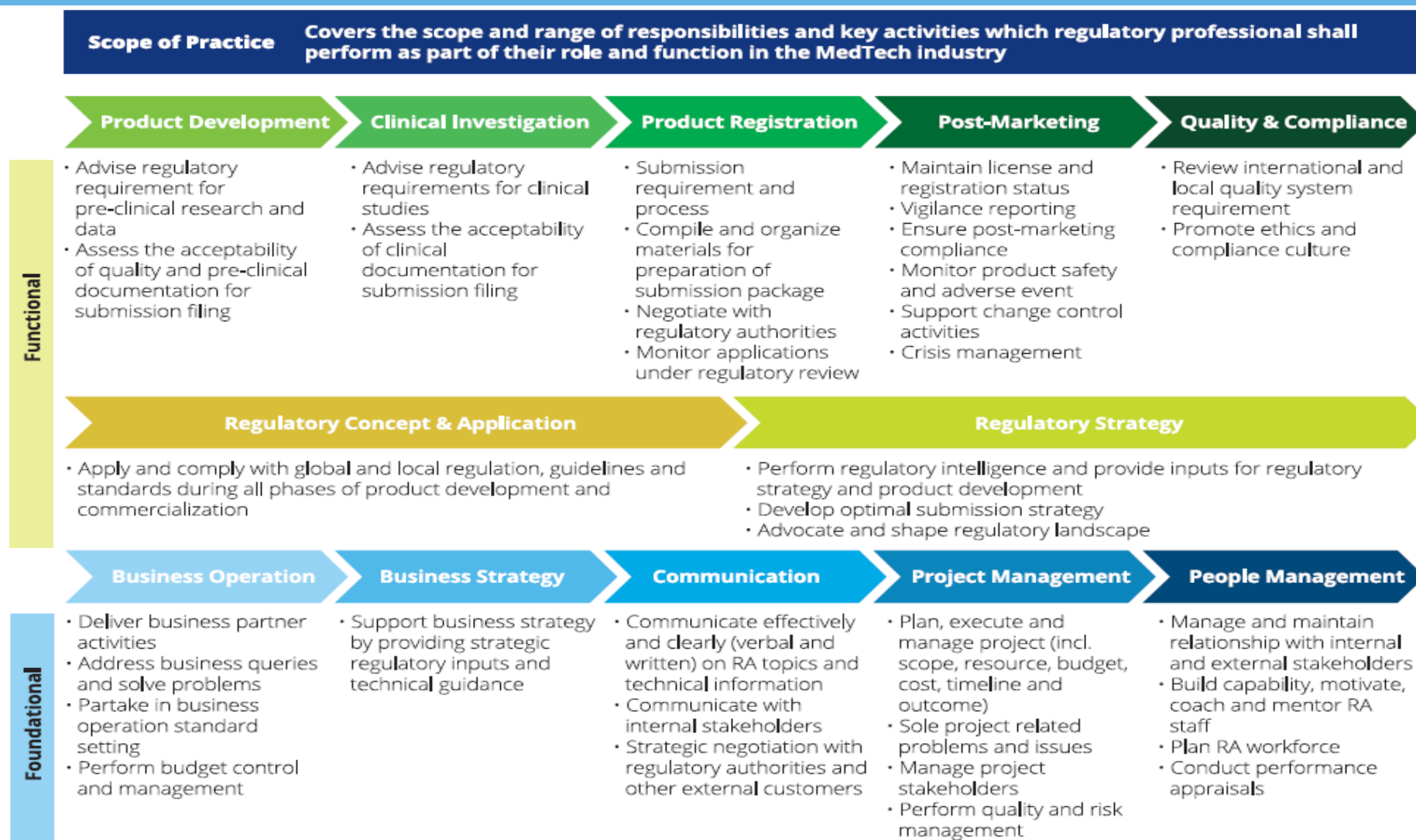
Business-related activities



Regulatory activities across all stages



A snapshot of detailed activities defined under “Scope of Practice”



* Please refer to White Paper p13 for more details

B- Competency



Domain

Covers key responsibilities and activities of RA professionals throughout all stages of the product lifecycle.



Competency

Lists the **knowledge, skills/abilities** required to perform all the activities identified in the domains.



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B- Competency

B

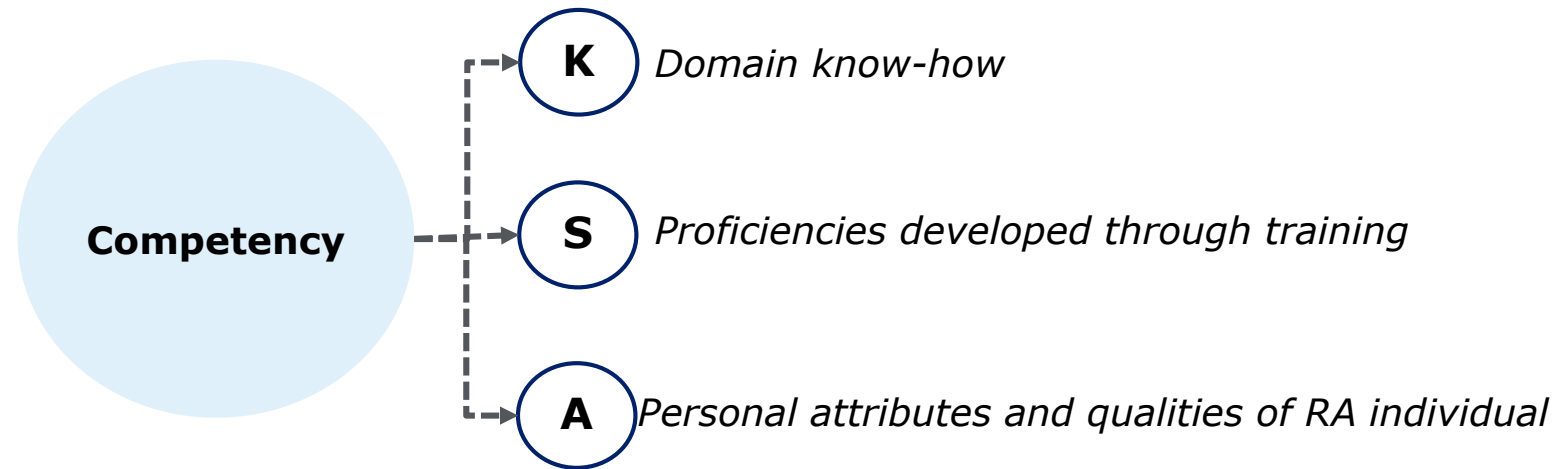
Competency

Knowledge

Institutional and regulatory professional knowledge

Skill/Abilities

Professional, interpersonal and business-related



Examples

Knowledge*

- Knowledge of laws, guidelines, procedures and concepts within Regulatory Affairs
- Reimbursement process and requirements

Skill/Abilities*

- Communication and negotiation skills
- Medical writing
- Strong business acumen/ Commercial awareness

* Please refer to White Paper (Appendix section p22-23) for more details

C- Professional Levels

Domain

Covers key responsibilities and activities of RA professionals throughout all stages of the product lifecycle.

Competency

Reflects the knowledge, skills/abilities required to perform all the activities identified in the domains.

Professional Levels

Refers to one of four professional/ career levels defined by **years of experience**

Proficiency Levels

Represent the required ability of an individual to perform specific competency at a certain professional level

C- Professional Levels

C









Professional Level

Level I
New professionals

Level II
Experienced professionals

Level III
Proficient professionals

Level IV
Seasoned professionals

		<i>Tenure</i>	<i>Expectations at Level</i>	<i>Example job titles</i>
	Level I	 1-2 years of RA experience	<ul style="list-style-type: none"> • Scientific, clinical or engineering backgrounds • Understand specific aspects of the healthcare product arena 	Coordinator and some associate positions
	Level II	 3-5 years of RA experience	<ul style="list-style-type: none"> • Understanding of regulator affairs through the product life cycle • Strong emphasis on technical aspects, scientific understanding and project management 	Specialist, assistant manager and manager positions
	Level III	 5-10 years of RA experience	<ul style="list-style-type: none"> • Move from the technical and tactical dimensions of RA and the product lifecycle into a more strategic role 	Manager, associate director, director
	Level IV	 >10 years of RA experience	<ul style="list-style-type: none"> • Strategic lead representing regulatory perspective while developing new approaches for business objectives 	Vice president, executive director, chief regulatory officer

D- Proficiency Levels

Domain

Covers key responsibilities and activities of RA professionals throughout all stages of the product lifecycle.

Competency

Reflects the knowledge, skills/abilities required to perform all the activities identified in the domains.

Professional Levels

Refer to one of four professional/career levels

Proficiency Levels

Represent the **required ability** of a RA individual across competencies and professional level

D- Proficiency Levels

D

Proficiency Level

Basic

Advanced

Expert

Mastery

Basic

Common knowledge or an understanding of **basic techniques and concepts**

Advanced

More **comprehensive and technical knowledge** of the particular task or skill and **self-sufficient** to perform assigned tasks independently

Expert

Deep and comprehensive knowledge of the particular task or skill and sufficient **expertise to deliver assignments** and to adapt to changing environments and demands

Mastery

Full expertise of the particular tasks or skill together with **high proficiency and specialised skills to run RA function** and complex projects

* Please refer to White Paper p15-18 for more details

D- Proficiency Levels

D

Proficiency Level

Basic

Advanced

Expert

Mastery

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Common knowledge or an understanding of **basic techniques and concepts**

Advanced

More **comprehensive and technical knowledge** of the particular task or skill and **self-sufficient** to perform assigned tasks independently

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Deep and comprehensive knowledge of the particular task or skill and sufficient **expertise to deliver assignments** and to adapt to changing environments and demands

Mastery

Full expertise of the particular tasks or skill together with **high proficiency and specialised skills to run RA function** and complex projects

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
Communication (verbal and written)	Be able to develop regulatory relevant business cases	N/A	Basic	Expert	Mastery
	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

* Please refer to White Paper p15-18 for more details

Bringing it to “Life” – an example...

C

Professional Level



RA Professional:

Justin Lee

Years of experience:

5 years

Professional Level:

Level 2

Bringing it to "Life" – an example...



Functional


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

Foundational

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

 Activities defined under "Scope of Practice" by product life cycle

C

Professional Level



RA Professional:

Justin Lee

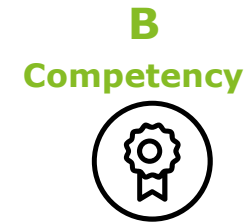
Years of experience:

5 years

Professional Level:

Level 2

Bringing it to "Life" – an example...



C
Professional Level



RA Professional:
Justin Lee
Years of experience:
5 years
Professional Level:
Level 2

Functional

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

Skills and abilities needed:

- maintain database and repositories of license and registration documents
- deal with the regulatory aspects of advertising, labelling and promotional materials
- **manage product safety and report adverse events to regulatory agencies and internal stakeholders**
- manage crisis

Foundational

Project Management

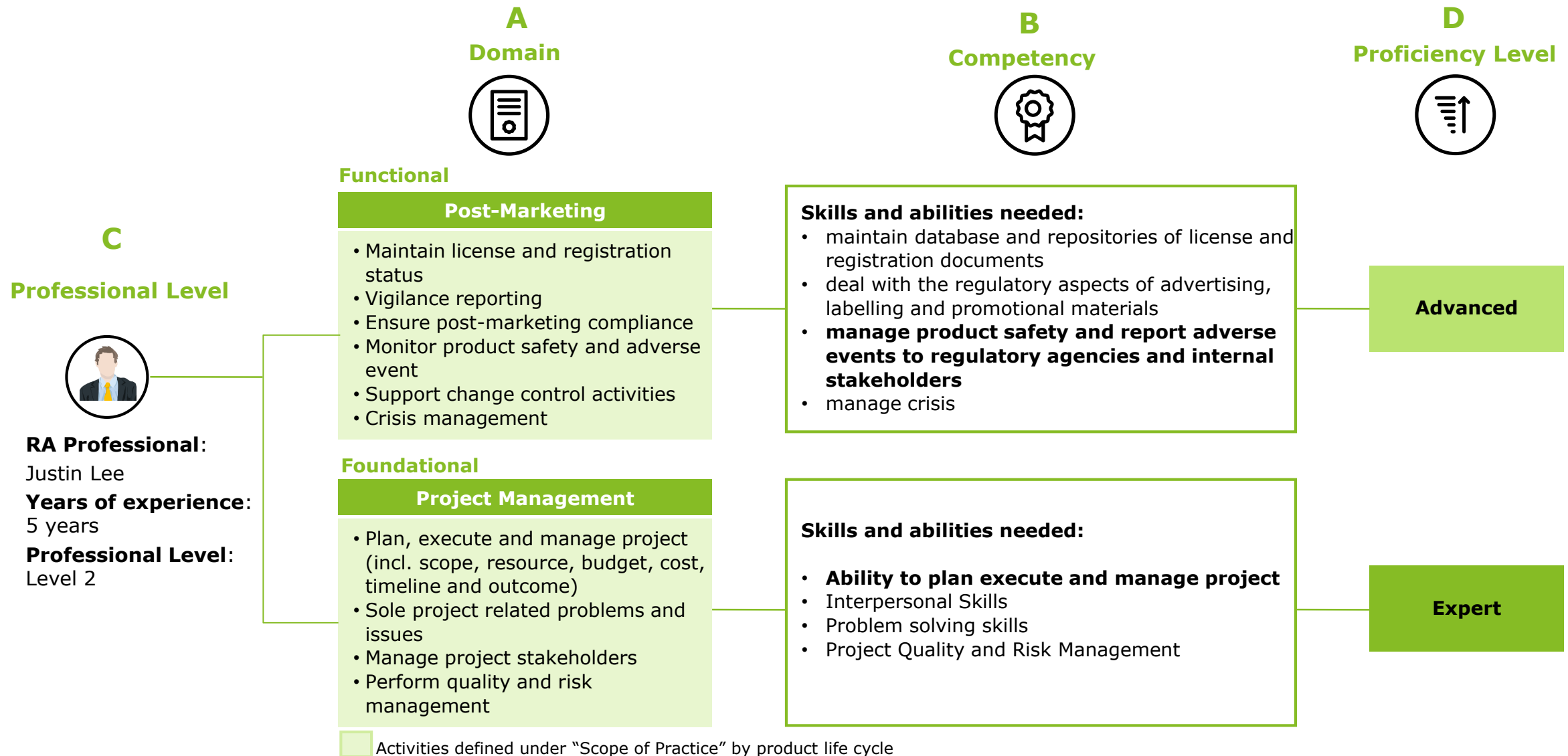
- Plan, execute and manage project (incl. scope, resource, budget, cost, timeline and outcome)
- Sole project related problems and issues
- Manage project stakeholders
- Perform quality and risk management

Skills and abilities needed:

- **Ability to plan execute and manage project**
- Interpersonal Skills
- Problem solving skills
- Project Quality and Risk Management




Activities defined under "Scope of Practice" by product life cycle

Bringing it to "Life" – an example...



Forward considerations

For MedTech companies in APAC

-  Use as a framework to **design career progression** of RA professionals in their organizations in APAC
-  Use as a guideline for designing **company cross-functional training program** to **upscale RA professionals' capabilities**
-  Use as catalyst to enhance **collaboration with regulators** – build an ecosystem consisting of regulators, academics, and government for **RA training program development**

For country regulatory bodies in APAC

-  Industry RA competency **framework can be enhanced to develop competency framework for country MedTech regulatory bodies** in APAC