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

GHWP Global Harmonization Working Party
Towards Medical Device Harmonization

APACMed
The voice of MedTech

Accenture Life Sciences
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Medical Device Regulatory Training Curriculum for Industry Professionals

White Paper

October 2020

Contents:

Executive Summary

The Medical Technology (MedTech) landscape is always evolving, with the industry facing new business and regulatory challenges every few years. The MedTech industry has recently taken center stage because of the dynamics of new innovative products and people with a technical background and interest in this intercultural, interpersonal profession, from manufacturing and supplying massive quantities of ventilators, personal protective equipment and sterilization equipment to inventing and distributing a rapidly expanding range of diagnostic tests. To keep up with such dynamic business and regulatory needs, MedTech professionals must continuously modernize and upskill their capabilities. To address this concern, Asian Harmonization Working Party (AHWP) / Global Harmonization Working Party (GHWP), and Asia Pacific Medical Technology Association (APACMed) had jointly developed a competency framework for industry regulatory professionals in August 2017, which served as a catalyst to initiate discussions and collaboration between RA professionals and the associated regulatory bodies. In 2020, there is a pressing need to rollout a standardized and appropriate training curriculum based on this framework, to initiate the capability development process.

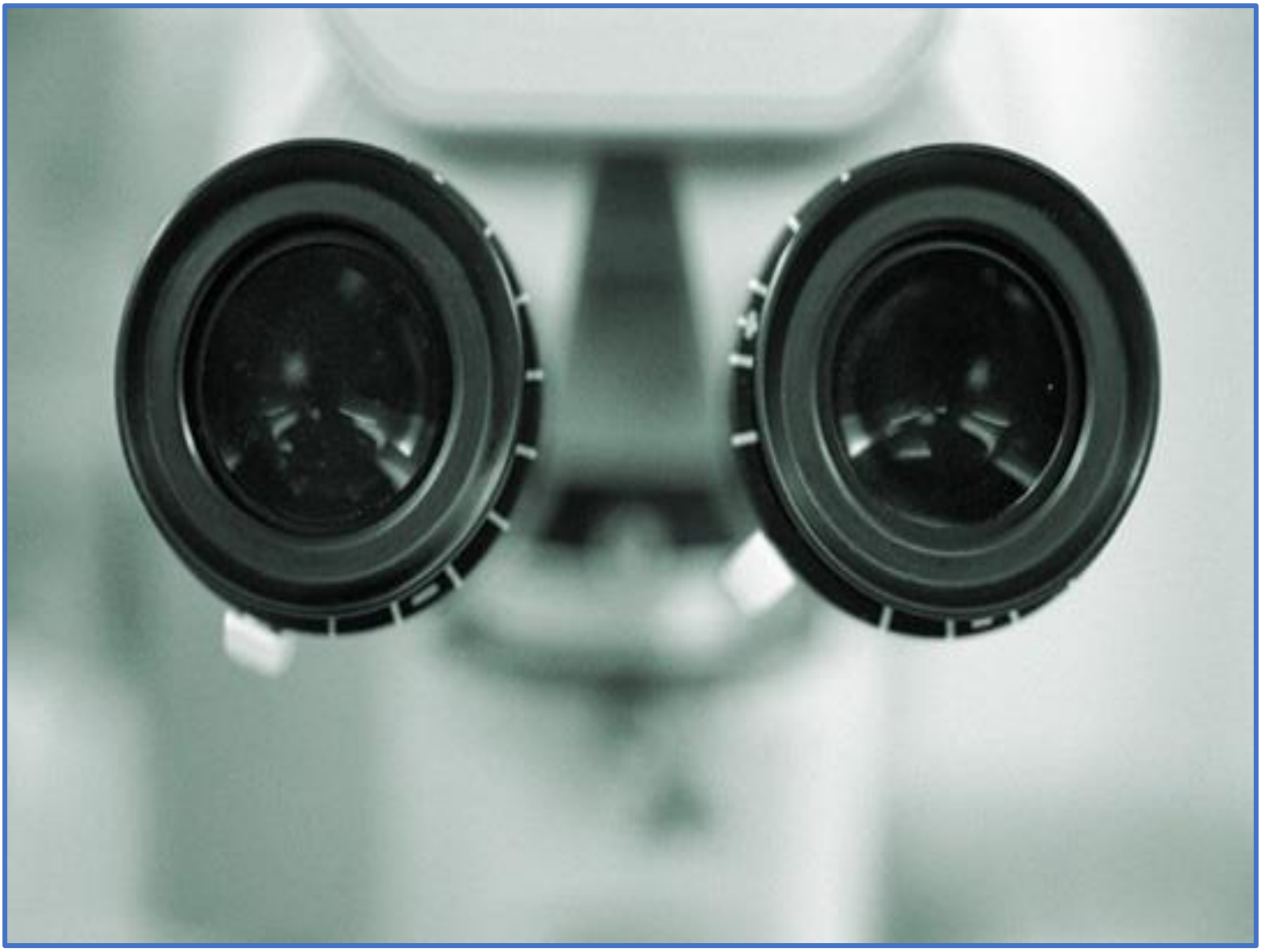
In the effort to draft a comprehensive training curriculum, AHWP/ GHWP, APACMed and Accenture have jointly conducted interviews and surveys with Regulatory Affairs (RA) leads of AHWP/ GHWP & APACMed member companies to get a holistic view of their training vision and current needs for regulatory trainings. This curriculum white paper focuses on defining the future direction of regulatory trainings for all AHWP/ GHWP and APACMed member companies.

The process to define the training curriculum consisted of 3 distinct steps. First, current state assessment was performed to map existing trainings in various member companies against specific skills/competency required from industry professionals, while identifying current gaps in the MedTech regulatory ecosystem. Then, targeted desktop secondary research was conducted to prepare and select trainings to bridge identified gaps across companies.

Next, based on primary and secondary data gathering, a master training repository was prepared to give an exhaustive list of trainings (130+ trainings) for MedTech regulatory industry professionals across companies. This repository has trainings across all competencies relevant to MedTech regulatory industry professionals with varying years of experience and can be used by company leads as an effective guide to curate training curricula for their employees.

Lastly, a training curriculum and this white paper were created using the current state assessment and master training repository. In the next few sections, the current state assessment and training curriculum approach, example & guiding principles for use are mentioned in detail.

Current State Assessment

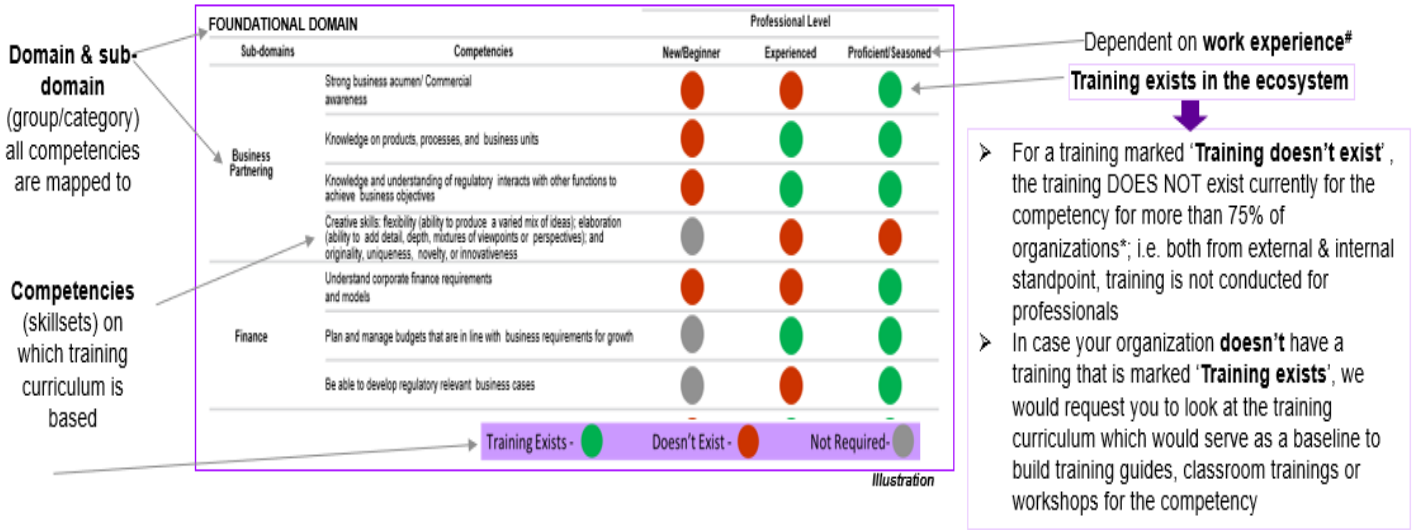


Current state assessment was performed using primary research tools such as interviews and surveys. 15 RA leads and Accenture SMEs were interviewed to understand their training vision & current needs for the MedTech regulatory industry. In parallel, surveys were rolled out to MedTech Regulatory professionals from over 20 companies, to collate lists of existing trainings taken by Regulatory professionals at these companies. A list of 99 trainings was created based on the survey responses, capturing name, description, duration and mode for each listed training.

After primary data was gathered, the current state was assessed with the following guidelines:

- Scope of assessment would cover AHWP/ GHWP and APACMed ecosystem with inclusion of firms of varying scale and capability maturity
- Trainings would be categorized into 2 major domains: Foundational & Functional. Foundational domain would focus on overarching roles and activities & functional domain would focus on day-to-day roles and functions (for more details, please refer to the AHWP/ GHWP APACMed curriculum framework)
- The assessment would identify key training gaps in MedTech Regulatory industry, that would then serve as focus areas for external training search and content development

An illustration of the current state assessment is provided below with explanation of each data point.



The assessment for each competency within the 2 domains is shown below:

FOUNDATIONAL DOMAIN

Sub-domains	Competencies	Professional Level (Total years of work experience)		
		New/Beginner (<2 yrs)	Experienced (3-7)	Proficient/Seasoned (8+)
Business Partnering	Strong business acumen/ Commercial awareness	Doesn't Exist	Doesn't Exist	Training Exists
	Knowledge on products, processes, and business units	Training Exists	Training Exists	Training Exists
	Knowledge and understanding of regulatory interacts with other functions to achieve business objectives	Doesn't Exist	Training Exists	Training Exists
	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	Doesn't Exist	Doesn't Exist	Doesn't Exist
Finance	Understand corporate finance requirements and models	Not Required	Doesn't Exist	Training Exists
	Plan and manage budgets that are in line with business requirements for growth	Not Required	Training Exists	Training Exists
	Be able to develop regulatory relevant business cases	Not Required	Doesn't Exist	Training Exists
Communication (verbal and written)	Effective communication on complex regulatory topics	Doesn't Exist	Training Exists	Training Exists
	Tailor communication style to listener's perspective to guide, influence, and convince stakeholders	Training Exists	Training Exists	Training Exists
	Conduct strategic negotiation with regulatory authorities	Not Required	Doesn't Exist	Doesn't Exist
	Medical writing covering pre & post marketing and vigilance surveillance	Training Exists	Training Exists	Training Exists

Training Exists - Doesn't Exist - Not Required-

FOUNDATIONAL DOMAIN

Sub-domains	Competencies	Professional Level (Total years of work experience)		
		New/Beginner (<2 yrs)	Experienced (3-7)	Proficient/Seasoned (8+)
Project Management	Plan, execute and manage project (incl. scope, resource, budget, cost, timeline and outcome)	Not Required	Doesn't Exist	Training Exists
	Problem solving skills	Doesn't Exist	Training Exists	Training Exists
	Interpersonal skills	Doesn't Exist	Doesn't Exist	Training Exists
	Understanding of statistics, data analysis from MedTech Regulatory perspective	Doesn't Exist	Doesn't Exist	Doesn't Exist
	Project quality and risk management	Doesn't Exist	Doesn't Exist	Doesn't Exist
People Management	Lead , motivate and train regulatory functions team	Not Required	Training Exists	Training Exists
	Contribute to workforce planning (incl. hiring, development, succession planning) and performance assessment	Not Required	Doesn't Exist	Training Exists
	Develop and maintain relationships with internal and external stakeholders	Not Required	Doesn't Exist	Training Exists
	Leadership Skills	Not Required	Doesn't Exist	Training Exists
Business Strategy	Understand regulatory requirements applied throughout the lifecycle to bridge business and clinical objectives with regulatory requirements	Doesn't Exist	Training Exists	Training Exists
	Analyse regulatory guidelines, policies and actions to determine regulatory and legal impact on the company	Doesn't Exist	Training Exists	Training Exists
	Strategic thinking. business processes, project planning	Not Required	Doesn't Exist	Training Exists

FUNCTIONAL DOMAIN		Professional Level (Total years of regulatory work experience)		
Sub-domains	Competencies	New/Beginner (<2 yrs)	Experienced (3-7)	Proficient/Seasoned (8+)
Premarketing	Provide strategic inputs and regulatory guidance for premarket approval	Not Required	Training Exists	Training Exists
	Review acceptability of quality, preclinical and clinical documentation and data, bio-statistical methods and analysis	Doesn't Exist	Doesn't Exist	Training Exists
	Prepare and compile regulatory submission packages	Training Exists	Training Exists	Training Exists
	Negotiate with regulatory authorities and perform other regulatory intervention	Training Exists	Training Exists	Training Exists
Postmarketing	Maintain databases and repositories of license and registration documents	Training Exists	Training Exists	Training Exists
	Deal with the regulatory aspects of advertising, labelling and promotional materials	Not Required	Training Exists	Training Exists
	Review and submit change controls to determine the level of change and consequent submission requirements	Not Required	Doesn't Exist	Training Exists
	Review and approve required reports, supplemental submissions to update and maintain product approvals and registrations	Training Exists	Training Exists	Training Exists
	Crisis Management	Doesn't Exist	Doesn't Exist	Doesn't Exist
	Manage product safety and report adverse events to regulatory agencies and internal stakeholders	Training Exists	Training Exists	Training Exists
Quality/Compliance	Promote ethics and create compliance culture	Training Exists	Training Exists	Training Exists
	Provide regulatory support during internal and external audits	Not Required	Training Exists	Training Exists
	Implement quality standards, design control, process control, supplier qualification	Not Required	Training Exists	Training Exists
	Products & processes risk assessment	Training Exists	Training Exists	Training Exists

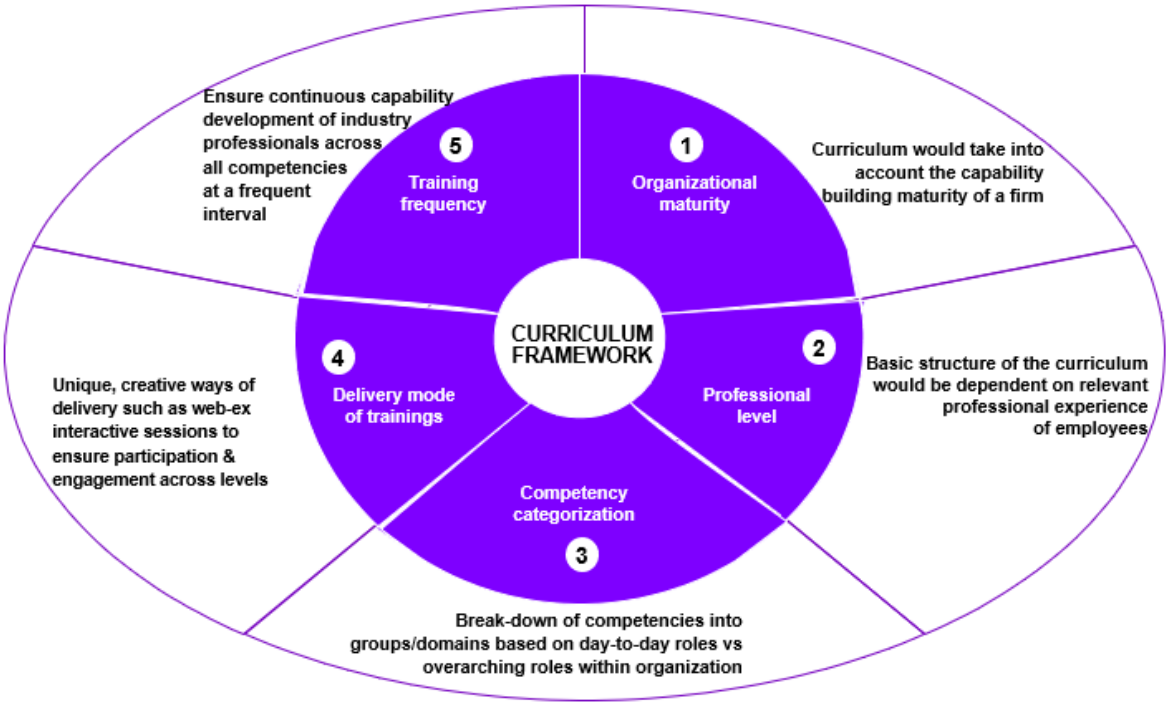
Training Exists - Doesn't Exist - Not Required-

FUNCTIONAL DOMAIN		Professional Level (Total years of regulatory work experience)		
Sub-domains	Competencies	New/Beginner (<2 yrs)	Experienced (3-7)	Proficient/Seasoned (8+)
Regulatory Knowledge and Application	Knowledge of laws, guidelines, procedures and concepts within Regulatory Affairs	Training Exists	Training Exists	Training Exists
	Ability to apply and implement the correct domestic laws, regulations, guidelines, standards, and procedures to obtain regulatory approval	Training Exists	Training Exists	Training Exists
	Ability to apply and implement the correct international laws, regulations, guidelines, standards, and procedures to obtain regulatory approval	Doesn't Exist	Training Exists	Training Exists
	Knowledge of guidelines, procedures and concepts for Digital Health	Doesn't Exist	Doesn't Exist	Doesn't Exist
	Knowledge of and complies with corporate internal policies and procedures	Training Exists	Training Exists	Training Exists
Regulatory Strategy	Provide regulatory intelligence for regulatory strategy & product development (incl. data processing, competitor analysis, environmental intelligence, due diligence support)	Not Required	Doesn't Exist	Doesn't Exist
	Develop optimal submission strategy and plans	Not Required	Doesn't Exist	Doesn't Exist
	Able to assess business impact with a given regulatory strategy	Not Required	Doesn't Exist	Doesn't Exist
	Impact and influence downstream decisions pertaining to testing, labelling, and clinical requirements	Not Required	Doesn't Exist	Doesn't Exist
	Advocate for and shape regulatory landscape	Not Required	Doesn't Exist	Doesn't Exist

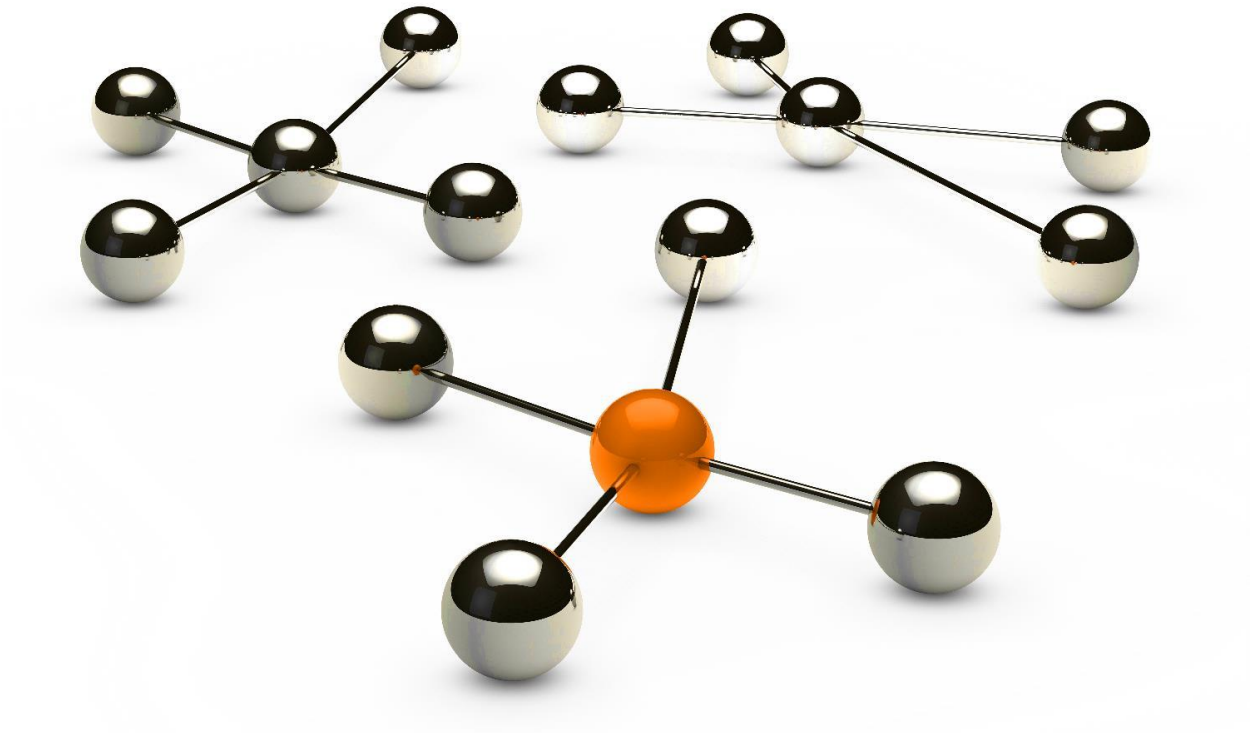
Approach to develop the Training Curriculum

Through primary research, five building blocks were identified which would shape the training curriculum – Organization Maturity, Professional Level, Competency Categorization, Delivery Mode and Training Frequency.

Companies with different levels of capability development maturity would be able to utilize the same training curriculum by making appropriate adjustments to modes and durations of the trainings.



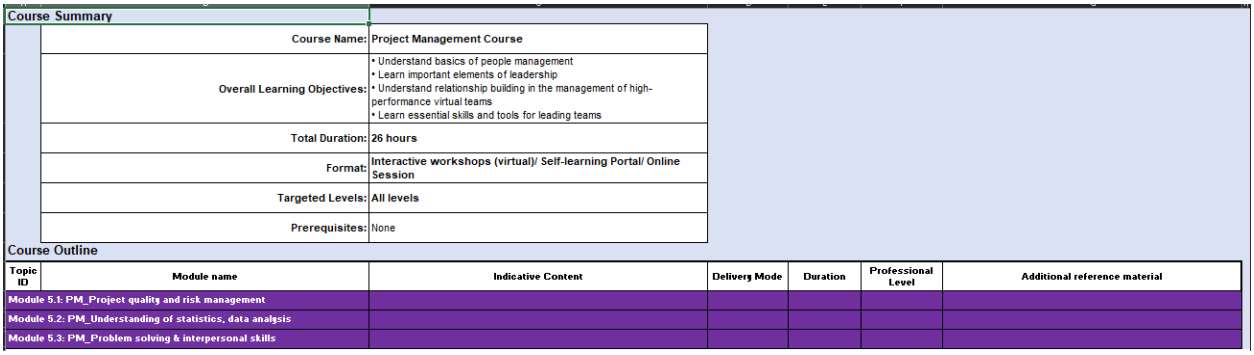
Training Curriculum Design



Using the exhaustive master training repository, a training curriculum of 11 broad courses was curated. Each course was broken down further into modules which covered 2-4 topics mapped to relevant competencies. Each topic can be covered in one session.

A capability development lead should consider the curriculum as a roadmap and assess their current plan against the curriculum. In case there is a module which is currently not present in their organization, they can leverage the indicative content for brief description to create trainings. Additionally, the master training repository can provide an exhaustive list of external / internal trainings for a deep dive into a module.

A screenshot of the curriculum plan is added below. The learning objective of the course is mentioned capturing key goals achieved after completion of the entire course. The duration & delivery mode in the training curriculum are indicative and can be changed depending on the capability development targets of the company.



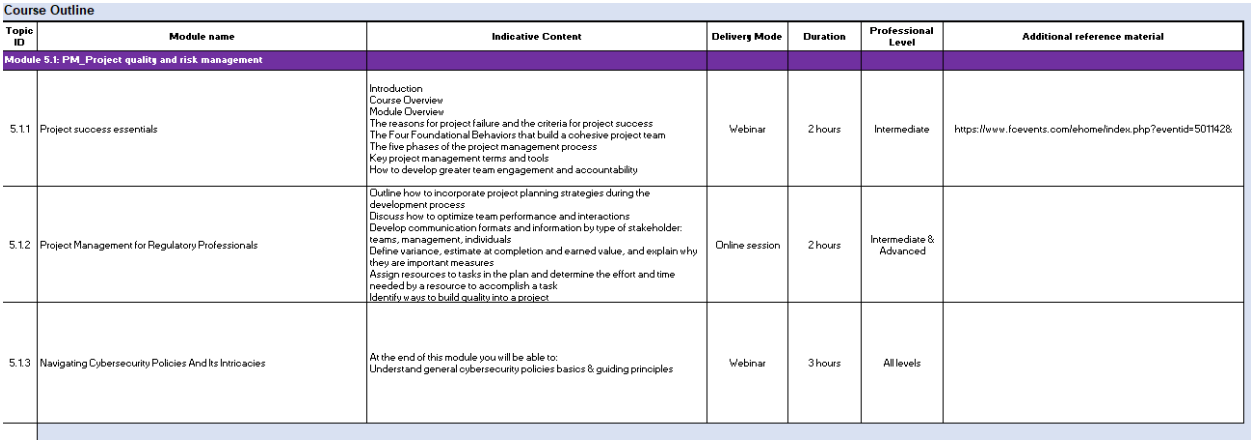
Course Summary

Course Name:	**Project Management Course**
Overall Learning Objectives:	• Understand basics of people management • Learn important elements of leadership • Understand relationship building in the management of high-performance virtual teams • Learn essential skills and tools for leading teams
Total Duration:	**26 hours**
Format:	**Interactive workshops (virtual)/ Self-learning Portal/ Online Session**
Targeted Levels:	**All levels**
Prerequisites:	None

Course Outline

Topic ID	Module name	Indicative Content	Delivery Mode	Duration	Professional Level	Additional reference material
Module 5.1: PM_Project quality and risk management						
Module 5.2: PM_Understanding of statistics, data analysis						
Module 5.3: PM_Problem solving & interpersonal skills						

Deep dive into one of the modules is captured below as an illustration. Indicative content along with delivery mode, duration & professional level is provided for each topic. Project Quality and Risk Management is a module within Project Management course. The module can be covered in 3 sessions over a duration of 7 hours. For the complete training curriculum comprising of 11 courses, please refer to the training curriculum excel.



Course Outline

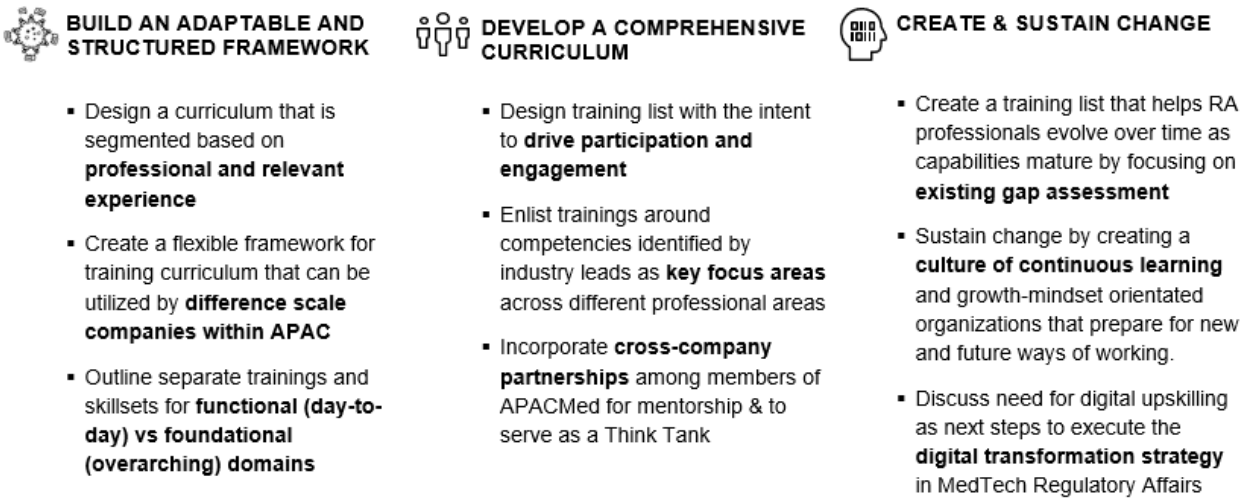
Topic ID	Module name	Indicative Content	Delivery Mode	Duration	Professional Level	Additional reference material
Module 5.1: PM_Project quality and risk management						
5.1.1	Project success essentials	Introduction Course Overview Module Overview The reasons for project failure and the criteria for project success The Four Foundational Behaviors that build a cohesive project team The five phases of the project management process Key project management terms and tools How to develop greater team engagement and accountability	Webinar	2 hours	Intermediate	https://www.foevents.com/ehome/index.php?eventid=501142&
5.1.2	Project Management for Regulatory Professionals	Outline how to incorporate project planning strategies during the development process Discuss how to optimize team performance and interactions Develop communication formats and information by type of stakeholder: teams, management, individuals Define variance, estimate at completion and earned value, and explain why they are important measures Assign resources to tasks in the plan and determine the effort and time needed by a resource to accomplish a task Identify ways to build quality into a project	Online session	2 hours	Intermediate & Advanced	
5.1.3	Navigating Cybersecurity Policies And Its Intricacies	At the end of this module you will be able to: Understand general cybersecurity policies basics & guiding principles	Webinar	3 hours	All levels	

Guidelines on the use of Curriculum

The most essential and relevant learning goals for MedTech Regulatory Industry Professionals have been outlined in the training curriculum. Goal is for AHWP/ GHWP and APACMed members to explain to their resources the identified learning goals & their importance in career progression.

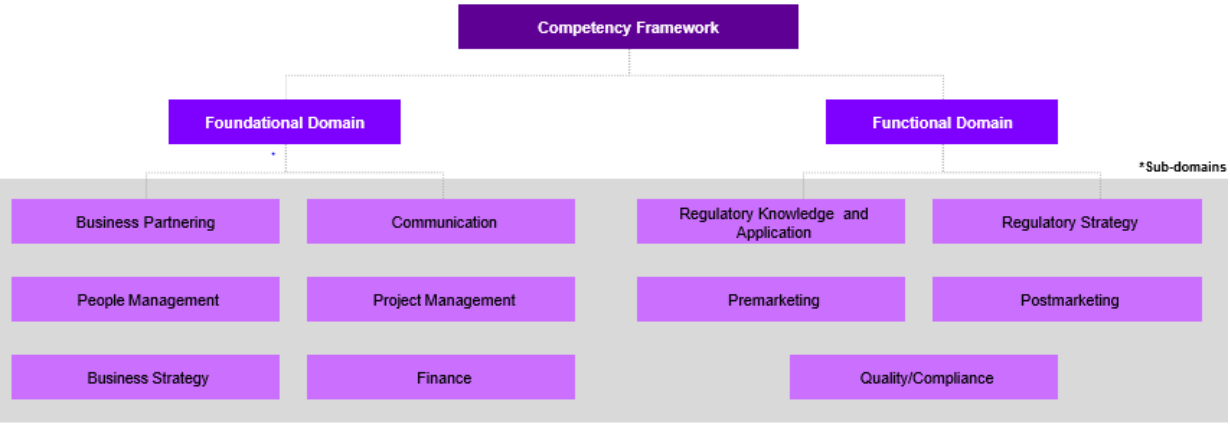
The training curriculum is a proposed capability development planning tool with suggested course durations, but it's the prerogative of the company capability leads to determine the scope and the sequence in which they would introduce the learning goals to their teams.

Accenture based the training plan on the below stated 9 guiding principles:



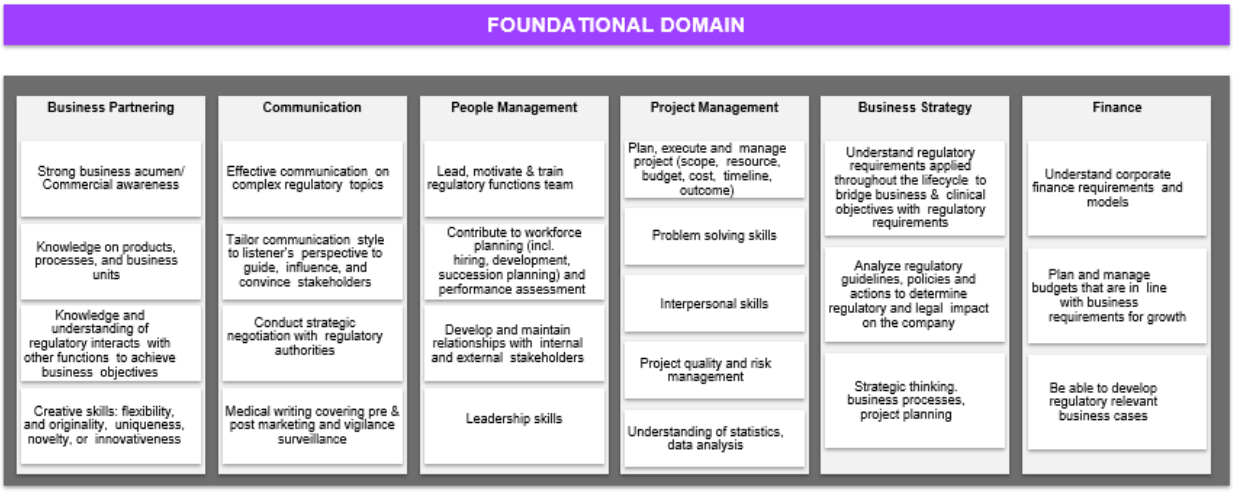
Appendices

Through interviews with RA leads, domains and sub-domains within competency framework are validated. The competency framework was prepared by AHWP/ GHWP & APACMed in collaboration with Deloitte in 2017.



Note: Domains reflect scope of responsibilities throughout the product lifecycle;
Competencies are identified within the sub-areas/ sub-domains such as Finance, Quality/ Compliance etc.

Within foundational domain, competencies are validated and modified based on inputs from RA leads



Note: Competencies have been re-validated & modified based on interviews with 15 RA leads and Accenture SMEs in MedTech Regulatory Affairs.

FUNCTIONAL DOMAIN

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

Note: Competencies have been re-validated & modified based on interviews with 15 RA leads and Accenture SMEs in MedTech Regulatory Affairs.

About AHWP/ GHWP

Established in 1996, the Asian Harmonization Working Party (AHWP) / Global Harmonization Working Party (GHWP) goals are to study and recommend ways to harmonize medical device regulations with members from Asia, Africa, Middle East and South America, and to work in coordination with the Global Harmonization Task Force aiming at establishing harmonized requirements, procedures and standards. GHWP was earlier called Asian Harmonization Working Party (AHWP) and has changed organization name in 2020 to better reflect the vision and representation of the Working Party. 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 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.

About Accenture

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

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

Acknowledgements

Our white paper benefitted immensely from the input and contribution provided by our steering committee and working group members. Their collective knowledge, experience and insights have helped to inform the best practice set out within. Each of the members have provided invaluable insight and served as a sounding board for our white paper through their thoughtful feedback, discussions and supporting information.

We'd like to thank the regulatory leads from across the MedTech industry, from within member base of AHWP/ GHWP and APACMed who that participated in this study. The interviews have provided a deeper understanding of the training vision & current state needs for APAC region regulatory trainings.

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