RAPS

Regulatory Competency Framework

2021

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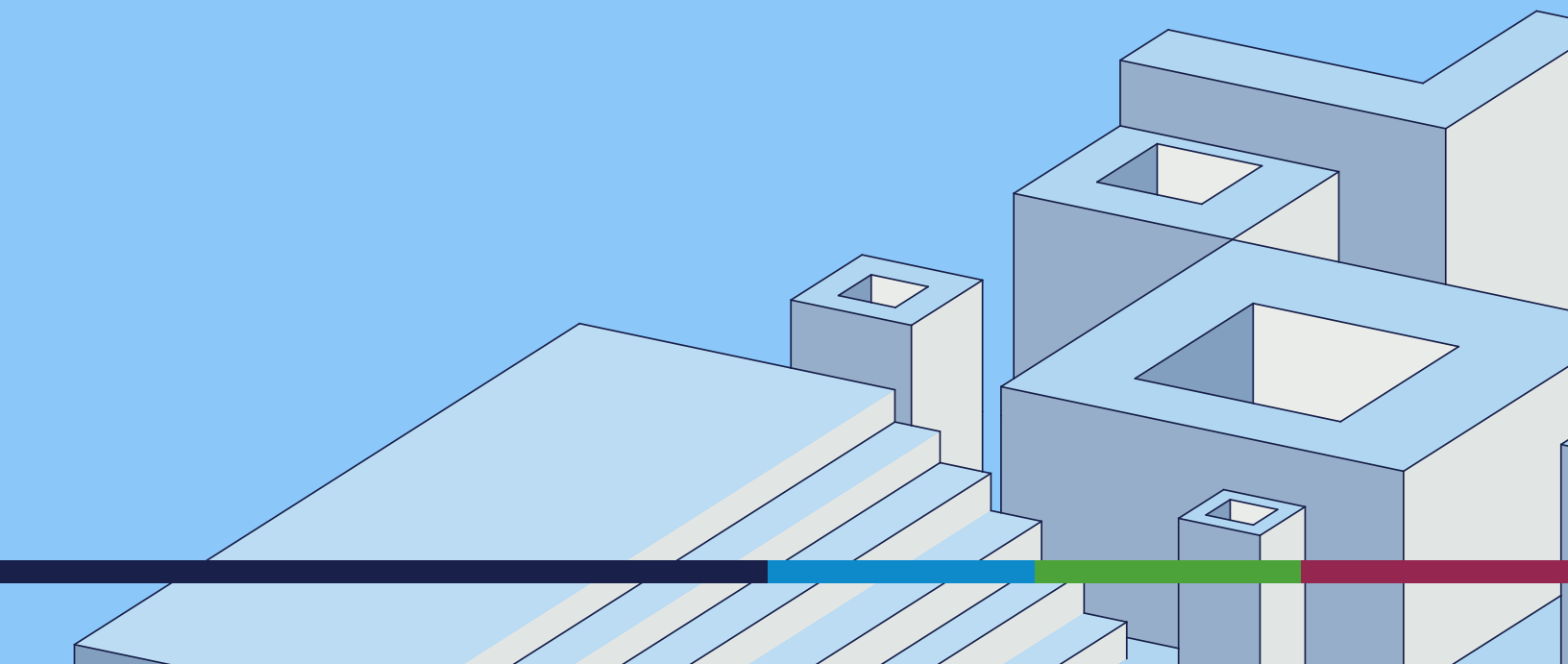


Introduction

Regulatory professionals play vital roles throughout the healthcare product lifecycle, from concept through product obsolescence. They provide strategic, tactical and operational direction and support for working within regulations to expedite the development and delivery of safe and effective products around the world. The continuous evolution of science and rapid change of the regulatory environment, health sector and general economics each shape the dynamic and expanding scope of the regulatory profession.

Like all professions, regulatory is based on a shared set of competencies. The following revised fourth edition of the Regulatory Competency Framework (RCF) from the Regulatory Affairs Professionals Society (RAPS) describes the essential elements of what is required of regulatory professionals at four key career and professional levels. The Framework explains the profession's basic competencies in clear, easy-to-understand statements and provides a foundation for regulatory professionals, regulators and employers to design training, develop curriculum, and manage professional and career development.

This framework is the result of years of ongoing research and development carried out by RAPS through the guidance of members and volunteer experts worldwide. Creating the Framework would not have been possible without the commitment and hard work of these dedicated individuals.

Care was taken to ensure the Framework applies to professionals in industry, government, research, clinical and other settings. The Framework is designed to be globally relevant and is not specific to any product sectors, regulatory systems or geographic regions. It is not intended to provide all the details of the scope of practice or responsibilities of all regulatory professionals. Nor is it intended to be a prescriptive description of the required knowledge, skills or competencies of the professional. It is a basic framework that may be applied to many different circumstances. It is intended to be customized, built upon and used to create more detailed profiles for specific situations.

Revisions to the 2021 Regulatory Competency Framework

Following a comprehensive review of the previous edition of the Regulatory Competency Framework, the reviewing task force recommended the following revisions:

- Revise description of the levels to reflect that senior professionals are expected to be able to perform and/or direct the competencies of junior professionals.
- Include professional titles that reflect the global workplace across a variety of organizational settings.

- Integrate the competencies contained within the previous Communication domain as a component of the Leadership domain.
- Provide enhanced differentiation between competencies across professional levels to distinguish expectations for roles that expand with professional growth.
- Reduce task-oriented competencies to focus on observable behaviors specifically relevant to regulatory professionals.
- Update descriptions of the Business Acumen, Scientific and Health Concepts, and Leadership Domains.
- Add new competencies reflecting the roles of a regulatory leader with regard to coaching and data management/IT practices.
- Consolidate and streamline competencies that are redundant in nature.
- Update language to reflect current business practices and trends.

Following the finalization of revisions, the Framework underwent a review by academic and industry experts, as well as by junior professionals to ensure relevancy across all professional levels.

Overview of the Regulatory Competency Framework

The Framework is based on two primary dimensions: levels and domains. Levels refer to four distinct professional levels, while domains reflect broad categories of professional responsibilities. For each level and domain, the Framework presents statements that describe what a regulatory professional is expected to do. These statements can be used as a foundation for developing organization-specific competency models.

Regulatory Competency Framework Levels

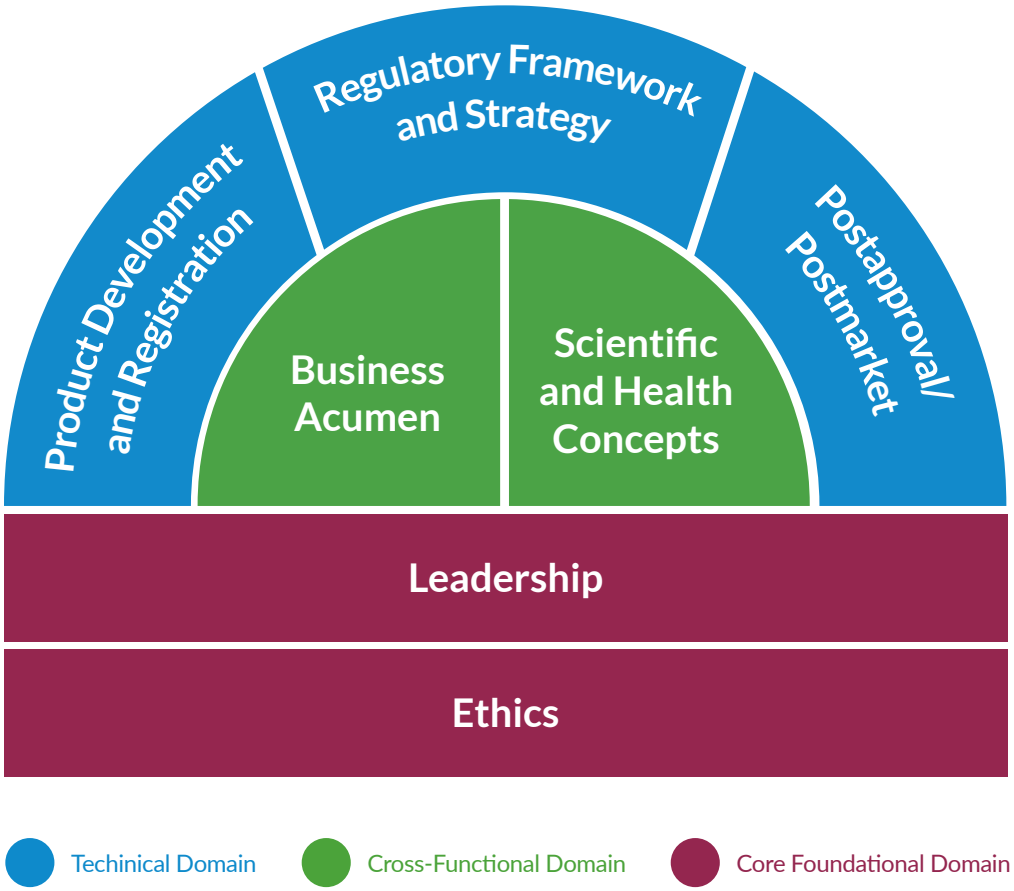
The competencies contained in this document have been organized by professional levels, which are defined by roles, expectations and individual proficiencies. The progression from Level 1 to Level 4 reflects increasing autonomy and expansion from more operational to more strategic activities, so that Level 1 is more directed and Level 4 is more directive. The Framework is organized based on an assumption that individuals operating at higher levels have mastered the competencies of preceding levels, for example, a Level 4 professional should be able to execute competencies in Levels 1–3 if necessary. In many cases, senior professionals are likely to direct and delegate operational activities rather than execute them.

While the Framework itself does not assign specific job titles to each level, examples of relevant titles are included in the summaries below. These are intended to provide guidance to both employees and employers and may need to be customized or adjusted to reflect different company sizes, structures, cultures and needs. Sample professional titles are included for various types of organizations (private, regulatory bodies, academia, etc.) to support adaptation of the Framework to organizational needs.

	Level			
	1	2	3	4
Description	Professionals at this level acquire knowledge related to the regulation of healthcare products, including regulatory frameworks, requirements, legislation and processes. Key Skills: Basic project management, communications, interpersonal skills and the ability to understand scientific and health concepts.	Professionals at this level have a strong foundation in the regulatory profession, including scientific, legal, policy and regulatory process management. Key Skills: Well-developed regulatory technical knowledge and skills. Regulatory Affairs Certification (RAC) is targeted to professionals at this level.	Professionals at this level understand and translate regulatory, scientific, operational and business knowledge into effective implementation plans and strategy. Key Skills: Integrates technical knowledge with management and strategy. Models desirable competencies to colleagues.	Professionals at this level take on the role of the strategic regulatory lead while developing new approaches for achieving or defining business objectives. Strategic planning and working with other teams throughout the product lifecycle—both within and outside the individual's organization—are among the most important responsibilities. Key Skills: Navigates ambiguity and demonstrates agility and other executive characteristics. Possesses and communicates strong understanding of the requirements, opportunities, risks and alternatives for developing and maintaining products. Sets the tone for ethical standards of behavior.
Proficiency	Foundational/ Operational/ Novice	Intermediate	Advanced	Expert
Learning Objective(s)	Acquire knowledge	Comprehend and apply knowledge	Analyze and synthesize knowledge	Evaluate knowledge
Private Sector	• Coordinator • Specialist • Associate	• Senior Specialist • Supervisor • Junior Manager • Manager	• Senior Manager • Director (private sector) • Senior Director • Asst. VP • "Head of" Roles	• Senior Director • Vice President • Executive Director • CRO (private sector) • Head or Chief of Regulatory • Global Vice President • Corporate Officer
Regulatory Agency/ Notified Body	• Reviewer • Auditor • Technical Auditor	• Reviewer (agencies) • Senior Reviewer • Lead Auditor	• Principal/ Experienced Reviewer (agencies) • Section Manager (agencies) • Head of Branch	• Division Director (agencies)
Academic/ Clinical Site Organization	• Teaching Assistant • Lecturer • Regulatory Coordinator	• Associate Professor • Adjunct Professor • Regulatory Analyst, Manager	• Professor	• Program Director • Department Chair
Consulting Organization	• Associate • Junior Consultant	• Consultant • Senior Consultant • Manager	• Principal Consultant	• Vice President • General Manager • Partner • Practice Lead

Regulatory Competency Framework Model Concept

The graphic representation of the Regulatory Competency Framework is designed to illustrate the relationship between the seven knowledge domains in which a regulatory professional pursues professional competency. Leadership and Ethics are the foundational domains, providing the underpinning for professional success. The cross-functional domains, Business Acumen and Scientific and Health Concepts represent knowledge content that is broadly relevant to those employed as regulatory affairs professionals. The technical domains, Product Development and Registration, Regulatory Framework and Strategy and Postapproval/Postmarket, specify the competency needs that reflect the specialized responsibilities of regulatory affairs work.



Technical Domains

Regulatory Frameworks and Strategy Domain

Description: Knowledge of regulatory frameworks and external environments and the ability to creatively apply these to innovative regulatory solutions throughout the product lifecycle

Knowledge: Regulatory Strategy Development, Data Management and Analysis, Product Planning, Market Strategy, Classification and Jurisdiction, Process and Procedures, Negotiation

Level 1	Level 2	Level 3	Level 4	
Researches requirements (local, national, international) and options for regulatory submissions, approval pathways and compliance activities.	Determines requirements (local, national, international) and options for regulatory submissions, approval pathways and compliance activities.	Assesses all requirements and potential obstacles for market access and distribution (federal, provincial/territorial/ state, reimbursement, purchasing groups, HTA, etc.) and develops creative solutions to address anticipated obstacles.	Contributes regulatory compliance elements in company's mission, vision, and strategy.	Classification and Jurisdiction
Monitors the regulatory environment (specific regulations, guidance and other relevant information by product types, geography, etc.), maintains information resources and disseminates changes/updates as needed.	Evaluates the regulatory environment and contributes by providing creative and innovative internal advice throughout the product lifecycle (e.g., concept, development, manufacturing, marketing) to ensure product compliance.	Develops and updates global, regional and multi-country regulatory strategy and seeks opportunities for innovative approaches to meeting regulatory requirements.	Develops the organization's national, regional and global regulatory position(s) and strategy based upon analysis and synthesis of internal and external intelligence (opportunities/risks).	Market Strategy
		Establishes working relationships and interfaces and with multiple government and non-government organizations having an impact on market access and distribution.	Interfaces with and establishes working relationships with multiple government and non-government organizations impacting market access.	Negotiation
Provides information entry into regulatory databases, submissions software programs, AI regulatory intelligence and decision systems, and creates reports as required.	Supervises data input activities, provides impact analysis and communication of report conclusions and recommendations.	Supervises regulatory operations functions to create and maintain regulatory information systems, that meet organization objectives.	Leads the development and execution of good regulatory practice and policy and regulatory systems to meet organization objectives.	Process and Procedures
Assists in the development of regulatory procedures and SOPs.	Identifies, collects, interprets and applies information on local, regional and global regulatory intelligence and other related information.	Distributes and implements regulatory intelligence to assist in the development of local, regional and global regulatory strategies.	Analyzes links between global, societal and economic trends; stakeholder concerns and regulatory issues and requirements; and the implications for regulatory strategy.	Process and Procedures Market Strategy Data Management and Analysis

Level 1	Level 2	Level 3	Level 4	
Assists in the development of regulatory procedures and SOPs.	Identifies the need for new regulatory procedures and SOPs, assures that departmental SOPs are developed to ensure regulatory compliance and participates in development and implementation.	Identifies the need for and manages the development, approval, and execution of new regulatory procedures and standard operating procedures (SOPs).	Is responsible for the overall development, creation, and implementation of regulatory systems and procedures to support the organization and its strategic objectives.	Process and Procedures
	Helps train stakeholders on current and new regulatory requirements to ensure organization-wide compliance.	Develops and manages programs that train stakeholders on current and new regulatory requirements to ensure organization-wide compliance.		Process and Procedures
Identifies requirements and potential obstacles for market access and distribution (federal, provincial/territorial state, reimbursement, purchasing groups, HTA, etc.) and the need for further regulatory guidance.		Identifies regulatory pathways for initial product designs and works with internal stakeholders to determine the final regulatory strategy.	Influences changing regulations and guidance.	Product Planning
	Assists in the development of regulatory strategy and updates product strategy across internal teams based upon regulatory changes.	Provides in-depth understanding and ability to incorporate regulatory strategies to expedite development for products intended for serious or life-threatening medical conditions or that address unmet medical needs (e.g., orphan, conditional approval, breakthrough therapy).	Leads efforts to incorporate regulatory strategies to expedite development for products intended for serious or life-threatening medical conditions or that address unmet medical needs (e.g., orphan, conditional approval, breakthrough therapy).	Regulatory Strategy Development

Product Development and Registration Domain

Description: Knowledge of the research and development, preclinical and clinical steps and related regulations in healthcare product development

Knowledge: Technical Management, Documentation, Regulatory Filing, Regulatory Guidance, Submission Management, Review Process Management

Level 1	Level 2	Level 3	Level 4	
Organizes and assists in the review of materials from preclinical and clinical studies and evaluates the information for inclusion in regulatory submissions.	Evaluates proposed preclinical, clinical and manufacturing changes for regulatory filing solutions and proposes plans/ strategizes (if appropriate) for changes that do not require submissions.	Reviews and assesses proposals to regulatory authorities on regulatory paths and clinical plans.	Participates in risk-based decisions on unique approvals (e.g., orphan drug, HDE, breakthrough) based upon patient needs and risk assessment.	Documentation Technical Management
Compiles and organizes materials for pre-submission reports and communications.	Provides knowledge and guidance on preapproval inspections, GCP inspections and clinical investigator relationships.	Monitors implementation of regulatory strategies relative to product and clinical safety issues identified during clinical phases.	Approves regulatory filing strategies for complex and/or critical products based upon proposed preclinical, clinical and manufacturing changes.	Documentation Regulatory Guidance

Level 1	Level 2	Level 3	Level 4	
Assembles and maintains regulatory files to support product submissions and assesses the potential impact from new guidance and regulations.	Provides regulatory input and technical guidance on global regulatory requirements to product development teams.	Provides strategic input and technical guidance on global regulatory requirements to product development teams.	Provides strategic input on regulatory requirements to R&D, clinical leads, and other executive leaders for complex and/or critical products.	Regulatory Filing
	Advises stakeholders of regulatory requirements for quality, preclinical and clinical data to meet applicable regulations.	Evaluates risks of product and preclinical and clinical safety issues during clinical phases and recommends regulatory solutions.	Leads the regulatory team's engagement in evaluation of risk and safety issues for complex and/or critical products and recommends regulatory solutions during pre-approval/clinical phases.	Regulatory Guidance
Represents regulatory on development teams with internal stakeholders and regulators and develops and organizes materials for these meetings.	Works with cross functional teams for interactions with regulatory authorities including panel meetings and advisory committees.	Leads cross-functional teams for interactions with regulatory authorities including panel meetings/ advisory committees.		Regulatory Guidance
Tracks the status of applications under regulatory review and provides updates to the development team.	Provides regulatory information and guidance for proposed product claims/ labeling.	Provides regulatory guidance on strategy for proposed product claims/labeling.		Review Process Management
Maintains logs of communication and outcomes with regulators and other relevant internal or external stakeholders.	Ensures clinical and nonclinical data are consistent with the regulatory requirements and support the proposed product claims.	Ensures that the clinical and nonclinical data—in conjunction with organizational objectives—are consistent with the regulatory requirements and support the proposed product claims.		Review Process Management Technical Management
Monitors and ensures regulatory review of publicly disseminated information on product submission approval status.	Monitors the progress of the regulatory authority review process through appropriate communication with the agency.	Ensures policies and procedures are in place for appropriate internal review and approval of regulatory submissions.		Review Process Management
	Communicates and interacts with regulatory authorities before and during the development and review of a regulatory submission through appropriate communication tools.	Leads key negotiations and interactions with regulatory authorities during critical stages of the development and review process.		Review Process Management
Supports the preparation of dossiers and submission packages for regulatory agencies.	May identify, monitor, and submit applicable reports (e.g., Serious Adverse Events) or notifications (e.g., changes in manufacturing) to regulatory authorities during the clinical research process.	Provides knowledge, critical analysis and may participate in preapproval inspections, GCP inspections and clinical investigator relationships.		Submission Management
Collects and organizes information on regulatory requirements for quality, preclinical and clinical data to meet applicable regulations.	Assesses the acceptability of quality, preclinical and clinical documentation for submission filing to comply with applicable regulations.	Evaluates proposed preclinical, clinical and manufacturing changes for regulatory filing solutions and proposes plans for changes that do not require submissions.		Technical Management

Postapproval/Postmarket Domain

Description: Knowledge of requirements and processes for maintaining a product on the market, reporting and surveillance

Knowledge: Recordkeeping, Monitoring, Product Management, Regulatory Notifications, Adverse Event Management, Change Management

Level 1	Level 2	Level 3	Level 4	
Manage systems to trigger and log regulatory reporting and to track, manage and report product-associated events.	Notifies organization and as necessary regulatory authorities as required regarding product safety issues to ensure compliance with local, regional, and global regulations.	Develops, implements and manages appropriate SOPs and systems to track, manage and report and communicate product-associated event complaints, recalls, market withdrawals and vigilance reports.	Leads and represents the regulatory team in product associated events, recalls and product withdrawals.	Adverse Event Management
Provides regulatory input and support and as necessary follow-up for inspections and audits.	Supervises or guides implementation of regulatory strategy and processes for handling recalls and communication to stakeholders (e.g., Dear Healthcare Professional letters, patient letters, distributor letters, and health authorities).	Adapts postmarket strategy in conjunction with cross-functional partners based on consideration of factors such as HTA, reimbursement, group purchasing pressures, state/provincial/regional restrictions and other legislative/regulatory requirements.		Adverse Event Management
Monitors and participates in the review of change requests to ensure compliance and the potential for regulatory submissions.	Submits notifiable changes and supplemental dossiers to the appropriate regulatory authorities to update product information and/or instructions for use to reflect current state of product knowledge.	Reviews and approves change controls to determine the level of change and consequent submission requirements, assesses potential impact on business objectives, and communicates that impact accordingly.	Integrates changes in postmarket strategy based upon consideration of factors such as HTA, reimbursement, group purchasing pressures, state/provincial/regional restrictions and other legislative/regulatory requirements to organization's business strategies.	Change Management
Performs data input.	Develops and implements processes involved with maintaining annual licenses, registrations and listings.	Ensures process is in place for review and approval of advertising and promotion to ensure regulatory compliance.	Reviews and approves enforcement action/responses.	Recordkeeping Monitoring
Monitors regulatory input and approval to advertising and promotion materials and activities to ensure regulatory compliance.	Reviews and recommends advertising and promotion to ensure regulatory compliance.	Develops, implements and manages systems to track required reports, supplemental submissions and other postmarketing commitments.		Recordkeeping
Tracks and maintains files on annual licenses, registrations and listings.	Assures postmarket regulatory requirements are met (e.g., required reports, supplemental submissions and other postmarketing commitments.)	Reviews and approves required reports, supplemental submissions and other postmarketing commitments to maintain product registrations.		Recordkeeping Product Management

Cross-Functional Domains

Business Acumen Domain

Description: Ability to leverage systems and processes to successfully operate a regulatory function to manage product and organizational risk

Knowledge: Industry-specific Knowledge, Operational Knowledge, Project Management, Quality Management and Continuous Improvement

Level 1	Level 2	Level 3	Level 4	
Participates in and supports continuous improvement processes as identified by the organization.	Continually improves the quality of policies, programs and services provided.	Leads integrated regulatory process and system improvement initiatives that will influence and build new capabilities for greater effectiveness and efficiencies.	Assess the data/ metrics/ performance etc. generated for continuous improvement opportunities within the organization and leverages such information to achieve regulatory objectives.	Continuous Improvement
Identify data that may be indicative of future trends that can be used to improve policies and procedures.	Frames issues with a thorough understanding of legislation, regulations, guidance, policy and directives.	Represent the organization with thorough understanding and communication of legislation, regulations, guidance, policy and directives.	Communicates regulatory and scientific issues with management and ensures management understanding of regulatory and scientific challenges.	Industry-specific Knowledge
			Provides recommendations to decision makers on regulatory strategies and options on new products or claims that balance business needs with regulatory oversight.	Industry-specific Knowledge
			Interprets and translates regulatory requirements into business opportunities.	Industry-specific Knowledge
			Supports due diligence process for company by ensuring effective regulatory assessment.	Industry-specific Knowledge
Preserves confidentiality of product information as appropriate.	Maintains knowledge of evolving regulatory information systems and makes recommendations regarding potential application within the organization.		Creates a culture of good information practices, protection/safeguarding of information.	Operational Knowledge
	Understands financial information used to make department/unit and organization-wide decisions and assists in the development and monitoring of department/unit budgets.	Uses financial analysis to generate, evaluate and act on strategic options and opportunities to support business decisions and manage and develop budget.	Understands and utilizes financial information to contribute to organizational business decisions and to make regulatory business unit decisions.	Operational Knowledge

Level 1	Level 2	Level 3	Level 4	
		Performs and/or supervises regulatory due diligence and identifies risks and opportunities for executive management (such as M&A).	Analyzes due diligence process for company sales, acquisitions, and mergers.	Operational Knowledge
Develops/expands project management capabilities as needed.	Identifies key resources and personnel for the project team - internal and external to their direct area of responsibility.	Assesses and approves work plans to ensure appropriate staging of activities and with clearly defined milestones.	Provides strategic guidance for resource and development planning.	Project Management
Tracks the staging of activities and milestones in regulatory work plans.	Creates work plans with appropriate staging of activities and with clearly defined milestones that match the organization's strategic objectives.		Reviews and approves creation and/or modification of operational infrastructures (e.g. processes, systems, structures, roles, metrics) to support strategic objectives for driving sustainable results.	Project Management
		Integrates qualitative and quantitative information to draw accurate conclusions.	Anticipates challenges, develops strategies and assures implementation to resolve complex issues with potential for significant regulatory impact.	Quality Management
		Evaluate corporate policies to mitigate regulatory risk to ensure adequate compliance to help the company achieve its business goals.	Oversees regulatory aspects of business relationships to ensure compliance and protect corporate interests.	Quality Management

Scientific and Health Concepts

Description: Understanding and application of evolving regulatory science to drive new approaches to improve the development, review and oversight of healthcare products

Knowledge: Regulatory knowledge, Application of Scientific and Clinical Advances, Healthcare Leadership

Level 1	Level 2	Level 3	Level 4	
Tracks scientific and/ or clinical advances that impact healthcare product development and regulations.	Assesses the scientific and/ or clinical advances that impact healthcare product development and regulations.	Manages or leads the process that monitors updates on scientific and clinical advances that impact healthcare product development and assesses the relationship to regulation and regulatory issues.	Identifies and proactively responds to scientific and/ or clinical advances that impact healthcare product development and regulations.	Application of Scientific and Clinical Advances
Engages in continuous learning activities to maintain technical competence in the product areas supported.	Participates in targeted education, clinical science, and evolving science study in order to meet regulatory requirements for emerging technologies.	Interprets evolving global regulatory science to develop new approaches to improve the development, review and oversight of healthcare products.	Serves as a thought leader in the understanding and application of evolving regulatory science to develop new approaches to improve the development, review and oversight of healthcare products.	Application of Scientific and Clinical Advances
	Participates in stakeholder groups to help shape science-based regulatory decision making.	Actively engages with stakeholder groups to help shape science based regulatory decision making.	Initiates and sponsors stakeholder groups to help shape science based regulatory decision making.	Healthcare Leadership

Core Domains

Ethics

Description: Ability to integrate and demonstrate core values, integrity and accountability throughout the organization and externally

Knowledge: Ethical Behaviors, Legal and Regulatory Requirements, Recognizing and Resolving Unethical Behavior

Level 1	Level 2	Level 3	Level 4	
Is aware of impact of ethical behavior by ensuring integrity in personal and organizational practices; respects people and principles, including professional, ethical and human values and may provide training to other departments regarding the importance of ethical behavior and decisions for regulatory compliance.	Demonstrates ethical behavior by ensuring integrity in personal and organizational practices; respects people and principles, including professional, ethical and human values; coaches and serves as a role model for others.	Seeks to ensure ethical behavior by ensuring integrity in personal and organizational practices; respects people and principles including professional, ethical and human values.	Champions ethical behavior by ensuring integrity in personal and organizational practices, respects people and principles, including professional, ethical and human values. Is sensitive to the potential for implicit bias and will raise any concerns through appropriate organizational channels.	Ethical Behaviors
			Ensures allocation of resources to enable ethical behaviors across the function and organization, as appropriate.	Ethical Behaviors
Sets an example by upholding the laws and regulations of the authorities under which they operate and the organization's internal/ external policies and directives through both personal action and more formal training processes.			Applies the Code of Ethics for the Regulatory Profession and develops an organizational code for regulatory and related staff that is consistent with the organizations' overall ethics programs and practices.	Legal and Regulatory Requirements
Aware of potential for conflicts of interest between work responsibilities and private affairs.	Takes all possible steps to prevent and resolve any real, apparent or potential conflicts of interest between one's official responsibilities and one's private affairs.	Coaches and mentors others to help them recognize potential organizational ethics and compliance issues.	Evaluates to assure compliance with conflict-of-interest guidelines and adherence with FCPA and other legislation directed at fraud and corruption.	Recognizing and Resolving Unethical Behavior
Raises and escalates, as appropriate, *potential* organizational ethics and compliance issues.		Raises and escalates, as appropriate, *significant* organizational ethics and compliance issues.		Recognizing and Resolving Unethical Behavior

Leadership

Definition: Ability to lead, manage, collaborate and communicate within the organization, with groups engaged in the development of good regulatory practice and policy, and within the regulatory profession

Knowledge: Leadership, Talent Management, Negotiation, Conflict Management, Collaboration, Communication, Relationship Management

Level 1	Level 2	Level 3	Level 4	
Demonstrates and advocates for working together in the spirit of openness, honesty and transparency that encourages engagement, collaboration, respectful interactions and trust.	Provides guidance and support to keep teams and the organization focused on objectives.			Collaboration
Seeks out diverse ideas, opinions and insights, and applies them in workplace.	Contributes to building a respectful, diverse and inclusive workplace, where decisions and transactions are transparent and fair.		Models, encourages and creates the conditions for an inclusive and respectful work environment. Acts as a catalyst and change agent for creating an inclusive and respectful work environment.	Collaboration
	Chooses the best alternative to achieve desired outcome or effect, giving consideration to risks, tradeoffs, timing and available resources.	Proactively manages and monitors progress against desired outcomes including working with others to establish and adjust contingency plans, revising and adapting processes, communicating success and learning from mistakes.	Ensures knowledge and lessons learned are shared across organizational boundaries. Leads thorough analysis of situations with appropriate attention to details and the big picture including consideration of impact at multiple levels of the system.	Communication
Demonstrates sensitivity and understanding of cultural considerations when dealing with others and actively seeks to understand one's own implicit biases and works to overcome them		Factors cultural considerations and impact into decision making.	Champions and cultivates a diverse workforce.	Communication
Clearly conveys information to peers, supervisors and other stakeholders.	Communicates with peers and supervisors and ensures alignment on issues, questions and goals.		Communicates updates to staff to gain alignment.	Communication
Communicates with knowledge, consistency and clarity to maintain integrity and impact of the message.	Aligns resources and discusses regulatory issues with supervisor and other relevant staff.	Aligns resources and discusses regulatory issues in cross-functional teams to ensure completion of project tasks	Develops and implements effective communication and engagement strategies with partners.	Communication
Creates clarity and direction amid complexity and develops solutions for self, colleagues and the organization.	Navigates the dynamics, alliances and competing requirements of the organization or business by providing solid rationale to support re.	Demonstrates the ability to build agreement and acceptance through his or her ability to present a compelling case for ideas, negotiate persuasively, and address disagreements constructively.	Makes tough or unpopular decisions where mission outcomes supersede the interests/concerns of individuals, constituencies or current situation.	Conflict Management Negotiation

Level 1	Level 2	Level 3	Level 4	
Connects and relates well with people who think and act differently than oneself.		Continually identifies and informs appropriate individuals on emerging trends, opportunities and threats.	Builds and sustains partnership across organizational boundaries and functions as well as outside the organization to achieve common goals and outcomes.	Leadership
Demonstrates composure and receptivity when presented with feedback and uses feedback as an opportunity to learn and improve.	Willingly accepts challenging assignments and new career opportunities that stretch and build capabilities.	Models humility by readily taking responsibility for errors, acknowledging opportunities for improvement, pursuing new ideas and perspectives and applying learning.	Monitors potential situations or incidents that may compromise individuals, the regulatory function or organization and intervenes in a positive manner to resolve the issue.	Leadership
		Articulates the organization's strategic vision in a manner than enables others to execute plans, tactics and actions.	Actively leads and engages in policy development, implementation and communication by framing emerging issues and contributing expertise in support of the organization's vision, strategy, priorities and obligations.	Leadership
		Makes informed decisions based on business frameworks and tools and give consideration to risks, tradeoffs, timing and available resources.	Makes timely and effective decisions, balancing the need for more information or analysis with the need to be decisive.	Negotiation
	Clearly conveys or exchanges information with stakeholders within and outside the organization in an appropriate and timely manner.	Delivers key messages effectively to a wide variety of audiences at all levels.	Communicates the organization's regulatory position to business partners.	Relationship Management
		Organizes, prepares for and facilitates effective meetings with internal and external stakeholders.		Relationship Management
Support and mentor direct colleagues in their personal development.	Mentors, manages and trains regulatory professionals. Able to provide constructive feedback to employees, support them and propose ideas for the employee's development and encourage their personal leadership.	Translates the organization's strategic objectives into meaningful goals for the team and individual. Challenges employees to explore new opportunities and to try challenging tasks.	Creates challenging tasks and development opportunities for employees within the organization and strives for the importance of personal development.	Talent Management
	Participates in talent management practices to support the development of a workforce that is well aligned with business needs.	Identifies and connects talent needs with talent resources and recruits, retains, manages and develops regulatory professionals to support the business strategy.	Actively engages in strategic and operational talent management practices (selection, promotion, development and engagement) to cultivate a workforce that is well aligned with current and emerging talent needs.	Talent Management

Acknowledgments

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