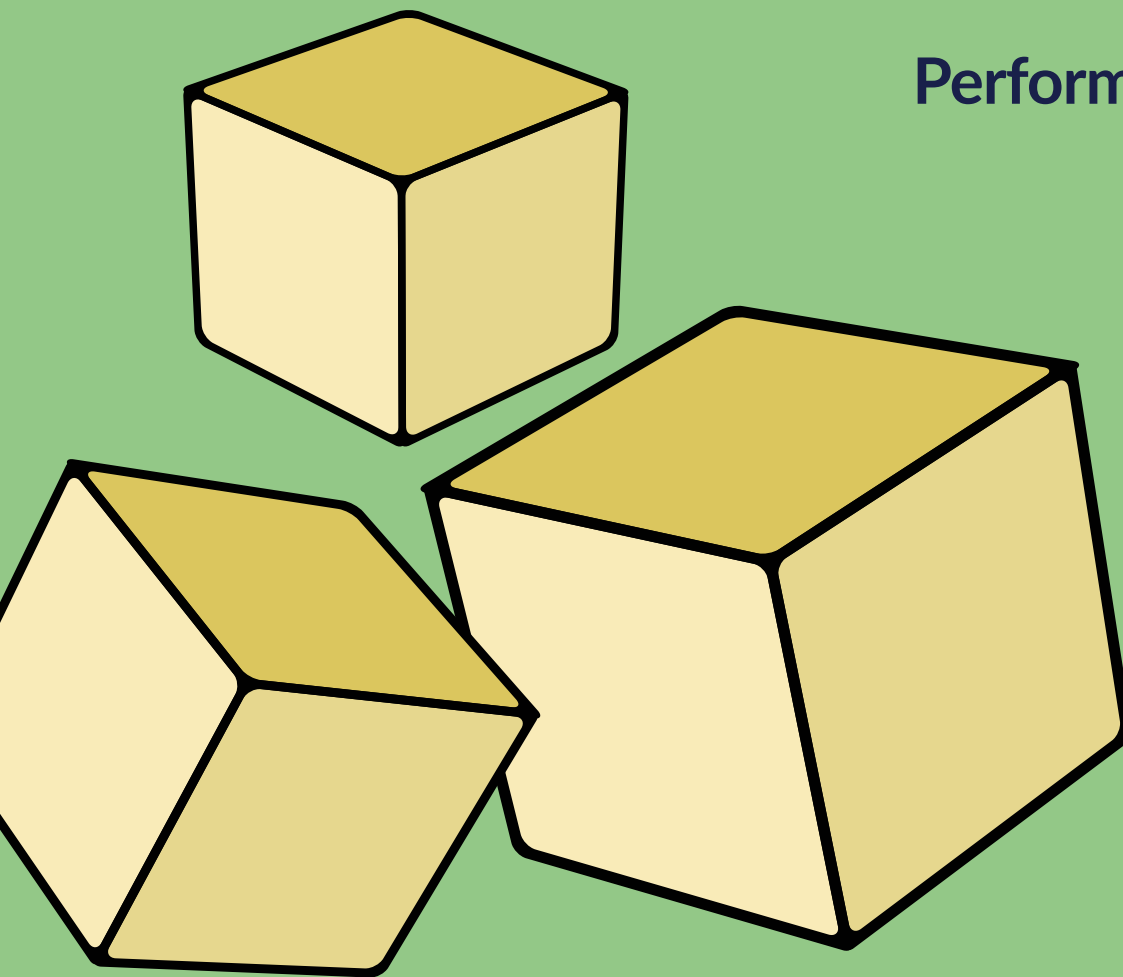


**RAPS**

# **Regulatory Competency Framework**

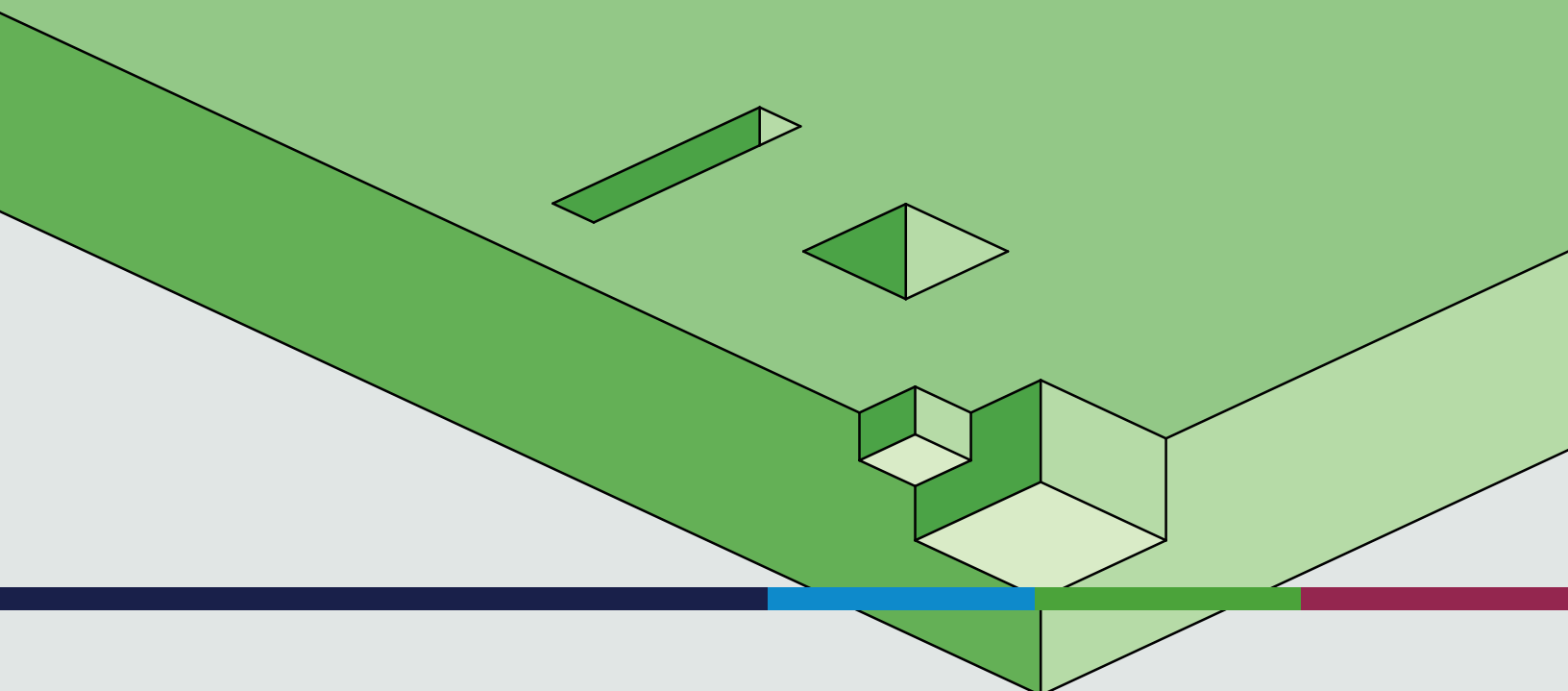
**Addendum:  
Performance Criteria**

**2022**



# Table of Contents

- 1 Introduction
- 2 Regulatory Frameworks and Strategy Domain
- 7 Product Development and Registration Domain
- 13 Postapproval/Postmarket Domain
- 17 Business Acumen Domain
- 21 Scientific and Health Concepts Domain
- 23 Ethics Domain
- 26 Leadership Domain
- 33 Acknowledgments



# Introduction



This guide is an addendum to the *Regulatory Competency Framework (2021)*

The 2022 Addendum extends the information provided in the 2021 Regulatory Competency Framework report. This document is intended to be used in conjunction with the 2021 report. The Addendum provides performance criteria for the seven knowledge domains and the four levels outlined in the 2021 report. Performance criteria are statements of behavior that can be objectively measured. They are illustrative in nature and not intended to be a definitive checklist. Examples can be adapted for use by individual professionals and Human Resources departments to aid with the hiring, development, and performance management of regulatory affairs professionals at all levels. We welcome your input. Please send feedback and use cases to [certification@raps.org](mailto:certification@raps.org).

# 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 product lifecycle

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

## Regulatory Strategy Development

Level	Competency	Criteria
1	N/A	
2	Assists in developing regulatory strategy and updates product strategy across internal teams based upon regulatory changes.	<ul style="list-style-type: none"> <li>• Collaborates with subject matter experts to gain a clear understanding of the product and effect on global regulations.</li> <li>• Understands regulatory requirements for the product and performs gap assessments against standards and regulations.</li> <li>• Communicates with other teams and key stakeholders on status of requirements and overall strategy for global markets.</li> <li>• Considers global ramifications when reviewing and approving documents.</li> </ul>
3	Provides an in-depth understanding and ability to incorporate regulatory strategies to expedite development of products intended for serious or life-threatening medical conditions or that address unmet medical needs (e.g., orphan, conditional approval, breakthrough therapy).	<ul style="list-style-type: none"> <li>• Uses one's in-depth product and regulatory knowledge to map alternate pathways for expedited approval.</li> <li>• Relies on industry experience to anticipate potential questions from health authorities.</li> <li>• Proactively engages with other teams to ensure data and evidence generated during product development clearly meet regulatory requirements.</li> <li>• Monitors and communicates changes in the regulatory environment, updating regulatory strategies accordingly.</li> </ul>
4	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).	<ul style="list-style-type: none"> <li>• Sponsors processes and procedures to ensure regulatory strategies are clear, agile (open to change/modifications/update), and executable.</li> <li>• Empowers stakeholders to examine and scrutinize plans and pathways to ensure robust strategies are developed.</li> <li>• Collaborates with business leadership to include regulatory insights during product-lifecycle management and prioritization.</li> </ul>

## Classification and Jurisdiction

Level	Competency	Criteria
1	Researches all jurisdictional requirements and options for regulatory submissions, approval pathways, and compliance activities.	<ul style="list-style-type: none"> <li>Understands and uses appropriate health-authority information to differentiate and justify product classification.</li> <li>Stays current with regulatory authority guidelines and engages in regulatory intelligence.</li> </ul>
2	Determines all jurisdictional requirements and options for regulatory submissions, approval pathways, and compliance activities.	<ul style="list-style-type: none"> <li>Organizes and communicates regulatory requirements for relevant product lines, cosmetic, drugs, biologics, and/or medical devices.</li> <li>Develops regulatory pathways, timelines, and overall strategies—including determining what type of submission to make—health authority communication, internal/external license requirements, etc.</li> </ul>
3	Assesses requirements and looks for potential obstacles to market access and distribution (federal, provincial/territorial/state, reimbursement, purchasing groups, HTA, etc.) and develops ways to address such obstacles.	<ul style="list-style-type: none"> <li>Evaluates the regulatory outcomes of initial product concepts/ market strategies and recommends future actions.</li> <li>Evaluates and interprets regulatory decisions to assess regulatory implications for approval through risk assessments.</li> <li>Assesses how local, regional, and national requirements and considerations affect regulatory submission/dossiers.</li> <li>Engages appropriate regulatory authorities' problem solving and additional information requests.</li> </ul>
4	Contributes regulatory compliance elements in the organization's mission, vision, and strategy.	<ul style="list-style-type: none"> <li>Ensures regulatory compliance of company standard operating procedures affecting internal stakeholders.</li> <li>Develops regulatory and quality compliance training programs for company personnel.</li> </ul>

## Product Planning

Level	Competency	Criteria
1	Identifies regulatory 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.	<ul style="list-style-type: none"> <li>Understands the basic regulatory requirements in the targeted markets.</li> <li>Participates in planning and problem-solving discussions.</li> </ul>
2	N/A	
3	Identifies regulatory pathways for initial product designs and works with internal stakeholders to determine the final regulatory strategy.	<ul style="list-style-type: none"> <li>Reviews regulatory strategies/plans to identify appropriate regulatory pathways for new products.</li> <li>Identifies the gap and effect of new and revised regulations and standards, and discusses possible solutions to create the regulatory strategy.</li> <li>Ensures regulatory strategies can be considered and implemented from the early stage of product designs.</li> </ul>
4	Influences changing regulations and guidance .	<ul style="list-style-type: none"> <li>Offers advice to competent authorities and industry trade associations on new and changing regulations and standards (e.g., innovative/break-through products, etc.).</li> <li>Influences regulatory trend, regulators, and senior leadership.</li> </ul>

## Negotiation

Level	Competency	Criteria
1	N/A	
2	N/A	
3	Establishes working relationships and interacts with governmental and non-governmental organizations that have authority over market access and distribution.	<ul style="list-style-type: none"> <li>• Defines and implements best-practice processes to ensure appropriate health-authority relations with an eye toward maximizing success.</li> <li>• Leads and facilitates interactions and negotiations with health authorities and notified bodies by modeling best practices.</li> <li>• Facilitates internal “lessons-learned” sessions to ensure best practices are known across the organization and followed.</li> <li>• Coaches junior and other teams’ members to analyze the regulatory landscape and determine best regulatory approaches for negotiation.</li> <li>• Advises senior management on best practices regarding rules of engagement with health authorities.</li> </ul>
4	Interacts with and establishes relationships with governmental and nongovernmental organizations with influence over market access.	<ul style="list-style-type: none"> <li>• Negotiates to resolve issues arising from meetings with health authorities.</li> <li>• Analyzes competing objectives, resource limitations, and differing perspectives to create resolution strategies.</li> <li>• Leads senior management through consensus building to refine resolution strategies prior to interacting with health authorities.</li> <li>• Uses strategies for resolution in future health authority interactions to resolve conflict and achieve positive regulatory outcomes to accomplish company objectives.</li> </ul>

## Market Strategy

Level	Competency	Criteria
1	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.	<ul style="list-style-type: none"> <li>• Uses available tools to monitor the regulatory environment.</li> <li>• Uses defined processes to review and assign priority levels to information, summarizing the information, drafting impact analysis, providing recommendations, and formatting and communicating those findings to internal stakeholders; archives the outcome for future reference.</li> </ul>
2	Evaluates the regulatory environment and provides creative and innovative advice throughout the product life cycle (e.g., concept, development, manufacturing, marketing) to ensure regulatory compliance.	<ul style="list-style-type: none"> <li>• Identifies the jurisdictional level and type of regulation that needs monitoring (e.g., agency versus specific division, country, discipline, therapeutic area, etc.).</li> <li>• Determines monitoring time interval (e.g., periodic or ongoing).</li> <li>• Develops monitoring processes.</li> <li>• Reviews and revises draft summaries, impact analyses, recommendations, and communications to internal stakeholders.</li> </ul>

Level	Competency	Criteria
3	Develops and updates global, regional, and multi-country regulatory strategy; crafts innovative approaches to meeting regulatory requirements.	<ul style="list-style-type: none"> <li>• Uses information derived from monitoring to develop and update project and/or therapeutic area regulatory strategy.</li> <li>• Uses innovative approaches for meeting regulatory requirements.</li> <li>• Conducts meetings with regulatory authorities to get approvals based on complying/justifying regulatory requirements.</li> </ul>
4	Develops national, regional, and global regulatory posture and strategy after analyzing and synthesizing internal and external intelligence (opportunities/risks).	<ul style="list-style-type: none"> <li>• Uses monitoring recommendations to develop and update organization regulatory strategy.</li> <li>• Coordinates with management and marketing to develop the regulatory market strategy in alignment with the organization's goal.</li> </ul>

## Process and Procedures

Level	Competency	Criteria
1	Provides information entry into regulatory databases, submissions software programs, and AI and decision systems; creates reports as required.	<ul style="list-style-type: none"> <li>• Provides data entry and information retrieval from internal databases and external resources, as appropriate.</li> <li>• Trains others in how to use and apply the organization's information systems and technology infrastructure.</li> <li>• Generates reports.</li> </ul>
	Assists in developing regulatory procedures and SOPs .	<ul style="list-style-type: none"> <li>• Updates SOPs, as needed.</li> </ul>
2	Supervises data entry, performs impact analysis; communicates report conclusions and recommendations.	<ul style="list-style-type: none"> <li>• Ensures data integrity in coordination with relevant stakeholders (e.g., clinical, non-clinical, CMC, R&amp;D, and QA).</li> </ul>
	Identifies the need for new regulatory procedures and SOPs, ensuring the SOPs lead to regulatory compliance; helps develop and implement SOPs.  Helps train stakeholders on current and new regulatory requirements to ensure organization-wide compliance.	<ul style="list-style-type: none"> <li>• Identifies and communicates necessary SOP revisions or creation.</li> <li>• Supports organization-wide training in regulatory compliance by instructing and coaching colleagues, as necessary.</li> </ul>
3	Supervises regulatory operations functions to create and maintain regulatory information systems , that meet organization objectives.	<ul style="list-style-type: none"> <li>• Ensures regulatory operations functions have the infrastructure and capability to meet regulatory intelligence needs.</li> </ul>
	Identifies the need for and manages the development, approval, and execution of new regulatory procedures and standard operating procedures (SOPs).  Develops and manages training programs to ensure organization-wide regulatory compliance.	<ul style="list-style-type: none"> <li>• Writes SOPs and ensures organizational implementation.</li> <li>• Evaluates regulatory requirements and if necessary, incorporates into SOPs.</li> <li>• Works with other departments (HR, training) to develop and implement training programs.</li> </ul>
4	Leads the development and execution of good regulatory practice and policy and regulatory systems to meet organization objectives.	<ul style="list-style-type: none"> <li>• Designs regulatory processes in support of organizational objectives.</li> <li>• Manages, supervises, and coaches regulatory staff and resources.</li> </ul>
	Is responsible for the overall development, creation, and implementation of regulatory systems and procedures to support the organization and its strategic objectives.	<ul style="list-style-type: none"> <li>• Identifies regulatory resource requirements to execute strategic objectives.</li> <li>• Creates and oversees regulatory affairs' budget; recommends effective use of organizational resources.</li> </ul>

# Process and Procedures, Market Strategy, and Data Management and Analysis

Level	Competency	Criteria
1	Assists in the development of regulatory procedures and SOPs.	<ul style="list-style-type: none"> <li>• Provides information to the regulatory intelligence system within the organization.</li> <li>• Performs data entry in tools /databases and assists with managing and analyzing data (e.g., in support of submissions, tracking approval, question types, commitments).</li> <li>• Executes established global regulatory procedures within the organization in conjunction with the commercial, reimbursement, operations, and legal (IP) teams.</li> <li>• Attends industry conferences to increase regulatory knowledge and intelligence source information.</li> <li>• Improves intelligence processes and procedures, as needed.</li> </ul>
2	Identifies, collects, interprets, and applies information about local, regional, and global regulatory intelligence.	<ul style="list-style-type: none"> <li>• Assesses regulatory intelligence gathering; communicates that information with internal stakeholders.</li> <li>• Manages regulatory initiative/use of tools/databases for management and analysis of data (e.g., in support of regulatory submissions approval tracking, question types, commitments); provides output to management.</li> <li>• Participates in the execution of global regulatory strategies within the organization in conjunction with commercial, reimbursement, operations, and legal (IP) teams.</li> </ul>
3	Distributes and implements regulatory intelligence to assist in the development of local, regional, and global regulatory strategies.	<ul style="list-style-type: none"> <li>• Helps lead regulatory intelligence governance within the organization and ensures appropriate stakeholders are aware of current and future requirements.</li> <li>• Drives use of proper framework to ensure consistent global regulatory strategies within the organization in conjunction with commercial, reimbursement, operations, and legal (IP) teams.</li> <li>• Designs regulatory initiative/use of tools/databases for management and analysis of data (e.g., in support of regulatory submissions approval tracking, question types, commitments).</li> <li>• Presents at industry conferences.</li> </ul>
4	Analyzes links among societal and economic trends, stakeholder concerns, and regulatory requirements; provides the implications for regulatory strategy.	<ul style="list-style-type: none"> <li>• Heads internal regulatory intelligence governance.</li> <li>• Ensures proper framework exists to facilitate global regulatory strategies within the organization in conjunction with commercial, reimbursement, operations, and legal (IP) teams.</li> <li>• Provides vision for regulatory initiatives/use of tools for management and analysis of data (e.g., in support of regulatory submissions approval tracking, question types, commitments).</li> <li>• Demonstrates leadership and influence in industry committees and trade groups and participates in industry conferences.</li> </ul>

# Product Development and Registration Domain

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

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

## Documentation and Technical Management

Level	Competency	Criteria
1	Organizes and assists in the review of materials from preclinical and clinical studies and evaluates the information for inclusion in regulatory submissions.	<ul style="list-style-type: none"> <li>Collects and organizes information per regulatory requirements for preclinical and clinical data, reports, and other applicable documentation.</li> <li>Evaluates the integrity of the documentation per applicable regulations requirement or deliverable checklist.</li> </ul>
2	Evaluates proposed preclinical, clinical, and manufacturing changes for regulatory filing solutions and proposes plans/strategies (if appropriate) for changes that do not require submissions.	<ul style="list-style-type: none"> <li>Collects proposed change requests and supporting evidence of preclinical, clinical, and manufacturing perspectives.</li> <li>Evaluates potential impact of existing regulatory strategy and proposes updated plans for changes.</li> <li>Researches guidance documents released by regulatory authorities to understand current regulatory agency thinking and devise the regulatory strategy.</li> </ul>
3	Reviews and assesses proposals to regulatory authorities on regulatory paths and clinical plans.	<ul style="list-style-type: none"> <li>Assesses documents, preclinical, and clinical documentation for submission filing to comply with applicable regulations and standards.</li> <li>Suggests improvements or updates to regulatory pathways, per review gap.</li> <li>Develops regulatory strategy for use in discussions and negotiations with regulatory authorities.</li> </ul>
4	Participates in risk-based decisions on unique approvals (e.g., orphan drug, HDE, breakthrough) based upon patient needs and risk assessment.	<ul style="list-style-type: none"> <li>Leads cross-functional team discussions to align on best regulatory approval pathway considering available quality, preclinical, clinical, and other technical supporting data.</li> <li>Advises stakeholders of regulatory pathway per regulatory authority's latest thinking about the unique approvals (e.g., orphan drug, HDE, breakthrough).</li> <li>Works with cross-functional teams to interact with regulatory authorities, including panel meetings and advisory committees.</li> </ul>

## Documentation and Regulatory Guidance

Level	Competency	Criteria
1	Compiles and organizes materials for pre-submission reports and communications.	<ul style="list-style-type: none"> <li>Prepares documentation for country submissions.</li> </ul>
2	Provides knowledge and guidance on pre-approval inspections, GCP inspections, and clinical investigator relationships.	<ul style="list-style-type: none"> <li>Advises stakeholders of regulatory requirements for quality, preclinical, and clinical data to meet applicable regulations.</li> <li>Represents regulatory on development teams with internal stakeholders and regulators, and develops and organizes materials for these meetings.</li> </ul>
3	Monitors implementation of regulatory strategies relative to product and clinical safety issues identified during clinical phases.	<ul style="list-style-type: none"> <li>Evaluates risks of product and preclinical and clinical safety issues during clinical phases and recommends regulatory solutions.</li> </ul>
4	Approves regulatory filing strategies for complex and/or critical products based upon proposed preclinical, clinical, and manufacturing changes.	<ul style="list-style-type: none"> <li>Leads the regulatory team engagement in evaluation of risk and safety issues for complex and/or critical products.</li> <li>Recommends regulatory strategy during preapproval/clinical phases.</li> <li>Leads cross-functional teams for interactions with regulatory authorities, including panel meetings/advisory committees.</li> </ul>

## Regulatory Filing

Level	Competency	Criteria
1	Assembles and maintains regulatory files to support product submissions and assesses the potential impact from new guidance and regulations.	<ul style="list-style-type: none"> <li>Understands market-specific regulatory filing requirements based on product type and classification.</li> <li>Generates and maintains accurate records for regulatory submissions.</li> <li>Provides input to gap assessments from new guidance and regulations.</li> <li>Maintains proficient operational knowledge on regulatory filing tools and software.</li> </ul>
2	Provides regulatory input and technical guidance on global regulatory requirements to product-development teams.	<ul style="list-style-type: none"> <li>Performs gap assessments from new regulations and guidance.</li> <li>Updates submission templates and SOPs to ensure new requirements are captured.</li> <li>Develops regulatory filing strategy as a core team member.</li> <li>Maintains expert operational knowledge on regulatory filing tools and software.</li> <li>Communicates submission filing status and relevant milestones to product development teams.</li> <li>Collaborates with the core team to address queries and deficiencies issued by the health authority.</li> </ul>

Level	Competency	Criteria
3	Provides strategic input and technical guidance on global regulatory requirements to product-development teams.	<ul style="list-style-type: none"> <li>• Develops filing strategy and determines the need for health authority consultations prior to regulatory filing.</li> <li>• Anticipates potential questions from health authority reviewers.</li> <li>• Maintains clear, timely communication with health authority reviewers throughout the filing process.</li> <li>• Trains regulatory team members on regulatory filing process for various product types.</li> </ul>
4	Provides strategic input on regulatory requirements to R&D, clinical leads, and executive leaders for complex and/or critical products.	<ul style="list-style-type: none"> <li>• Represents and emphasizes regulatory filing requirements at the leadership level across R&amp;D, clinical, quality, and other business functions to ensure deliverables generated from various functions clearly meet regulatory filing requirements and support organizational strategy.</li> <li>• Develops and manages regulatory-filing budgets and health-authority meetings.</li> <li>• Tracks submission outcomes and incorporates best practices into departmental templates and SOPs.</li> <li>• Trains department on regulatory-filing best practices.</li> <li>• Tracks and trends deficiencies and outcomes of regulatory filings for continuous improvement.</li> </ul>

## Regulatory Guidance

Level	Competency	Criteria
1	Represents regulatory on development teams with internal stakeholders and regulators; develops and organizes materials for these meetings.	<ul style="list-style-type: none"> <li>• Ensures appropriate management of team meetings and tracking of actions and commitments.</li> <li>• Consults with manager or other more experienced personnel for guidance when faced with challenging strategies or group dynamics.</li> <li>• Coordinates communication in a timely manner with appropriate health authority administrative contacts.</li> </ul>
2	Advises stakeholders of regulatory requirements for quality, preclinical, and clinical data to meet applicable regulations.	<ul style="list-style-type: none"> <li>• Provides regulatory strategy as appropriate for drug/biologics development, medical devices, and other product types according to the relevant regional guidance, regulations, and standards.</li> <li>• Considers alternate approaches to meet business needs and/or if not clearly defined in related resources.</li> <li>• Communicates project or business impact based on potential regulatory strategies.</li> </ul>
	Works with cross functional teams for interactions with regulatory authorities, including panel meetings and advisory committees.	<ul style="list-style-type: none"> <li>• Coordinates proper planning, logistics, and rehearsals prior to external meetings.</li> <li>• Assists leadership with external meeting materials preparation.</li> <li>• Compiles meeting minutes and actions/commitments and coordinates final meeting materials review.</li> </ul>

Level	Competency	Criteria
3	Evaluates risks of product, preclinical, and clinical safety issues during clinical phases; recommends regulatory solutions.	<ul style="list-style-type: none"> <li>• Confirms risk mitigation plans exist in relation to strategy to ensure alignment with business needs.</li> <li>• Guides others to formulate alternate approaches to meet business needs and/or if not clearly defined in related resources.</li> </ul>
	Leads cross-functional teams in interactions with regulatory authorities, including panel meetings/ advisory committees .	<ul style="list-style-type: none"> <li>• Guides stakeholders and ensure proper planning and rehearsals prior to external meetings.</li> <li>• Participates in external meetings with appropriate health authorities and/or notified bodies.</li> <li>• Reviews and approves meeting minutes, actions/commitments, and final meeting materials with other stakeholders.</li> </ul>
4	Leads the regulatory team's engagement in evaluating risk and safety issues for complex and/or critical products; recommends regulatory solutions during pre-approval/clinical phases.	<ul style="list-style-type: none"> <li>• Oversees the team's strategy and plan for agency/notified bodies interactions and meetings.</li> <li>• Approves risk-mitigation strategy as aligned with the organization's risk register or risk tolerance.</li> <li>• Leads external meetings with appropriate health authorities and/or notified bodies.</li> <li>• Represents the organization along with the team in complex or contentious interactions.</li> </ul>

## Review Process Management

Level	Competency	Criteria
1	Tracks the status of applications under regulatory review and provides updates to the development team.	<ul style="list-style-type: none"> <li>• Uses trackers, logs, and other tools as appropriate to maintain clear records on the progress of regulatory submissions.</li> <li>• Communicates the status of regulatory submissions to research and development (R&amp;D) in a timely manner.</li> </ul>
	Maintains logs of communication and outcomes with regulators and other relevant internal or external stakeholders.	<ul style="list-style-type: none"> <li>• Uses trackers, logs, and other tools as appropriate to maintain clear records of communication with regulatory authorities and internal supervisors.</li> </ul>
	Monitors and ensures regulatory review of publicly disseminated information on product submission approval status.	<ul style="list-style-type: none"> <li>• Supports regulatory review of press releases, marketing materials, and other publicly disseminated information related to product submission approval status to ensure regulatory compliance.</li> </ul>
2	Provides regulatory information and guidance for proposed product claims/ labeling.	<ul style="list-style-type: none"> <li>• Educates stakeholders on the process of using a claims matrix to manage regulatory claims based on regulatory classification of product and applicable standards for supporting evidence.</li> </ul>
	Ensures clinical and nonclinical data are consistent with regulatory requirements and support the proposed product's claims.	<ul style="list-style-type: none"> <li>• Evaluates regulatory requirements for quality, bench, preclinical, and clinical data needed to support desired claims.</li> <li>• Conducts regulatory review of press releases, marketing materials, and other publicly disseminated information related to product submission approval status to ensure regulatory compliance.</li> </ul>
	Monitors the progress of the regulatory authority review process through appropriate communication with the agency.	<ul style="list-style-type: none"> <li>• Facilitates and supports senior regulatory team members by filing communications and disseminating to appropriate stakeholders.</li> </ul>
	Communicates and interacts with regulatory authorities before and during the development and review of a regulatory submission through appropriate communication tools.	<ul style="list-style-type: none"> <li>• Provides notice of upcoming submissions to regulatory authority contacts, as appropriate, to ensure timely review.</li> <li>• Supports senior regulatory leadership by facilitating and coordinating the development of timely responses to regulatory authorities' queries.</li> </ul>

Level	Competency	Criteria
3	Provides regulatory guidance on strategy for proposed product claims/labeling.	<ul style="list-style-type: none"> <li>Develops (as needed) and enforces the use of a claims matrix and regulatory review process for the organization.</li> <li>Creates and maintains claims matrices for product lines, as appropriate.</li> </ul>
	Ensures that the clinical and nonclinical data—in conjunction with organizational objectives—are consistent with the regulatory requirements and support the proposed product claims.	<ul style="list-style-type: none"> <li>Advises stakeholders of regulatory requirements for quality, bench, preclinical, and clinical data needed to support desired claims and the potential risks associated with noncompliance.</li> <li>Provides regulatory review of clinical and nonclinical study plans and protocols to ensure they will obtain the objective evidence needed to support desired claims.</li> <li>Provides regulatory review of marketing material, referencing clinical, and nonclinical study reports to ensure regulatory compliance.</li> </ul>
	Ensures policies and procedures are in place for appropriate internal review and approval of regulatory submissions.	<ul style="list-style-type: none"> <li>Develops and enforces an internal regulatory submission review process to ensure all sections of the submission comply with requirements.</li> <li>Develops and enforces a cross-functional review process for regulatory submissions.</li> <li>Communicates the status of regulatory submission preparation to stakeholders as appropriate.</li> </ul>
	Leads key negotiations and interactions with regulatory authorities during critical stages of the development and review process.	<ul style="list-style-type: none"> <li>Collaborates with subject matter experts (SMEs) to develop technically accurate and strategic responses to regulatory authority queries with the objective of securing approval for the regulatory submission.</li> <li>Negotiates and interacts through appropriate communication tools (e.g., meetings, email, etc.) with regulatory authorities before and during the product development and review process to facilitate submission approval.</li> <li>Identifies appropriate escalation strategies, if/when needed during regulatory submission review.</li> </ul>
4	N/A	

## Submission Management

Level	Competency	Criteria
1	Supports the preparation of dossiers and submission packages for regulatory agencies.	<ul style="list-style-type: none"> <li>Gathers and checks information for submission documents in accordance with recommended health authority guidance documents for format and consistency.</li> </ul>
2	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.	<ul style="list-style-type: none"> <li>Communicates with regulatory authorities notifications of safety, efficacy, and quality updates through appropriate submission processes and following health.</li> </ul>
3	Provides knowledge, critical analysis and may participate in pre-approval inspections, GCP inspections and clinical investigator relationships.	<ul style="list-style-type: none"> <li>Actively participates and prepares for preapproval inspections, quality audits, and other clinical activities.</li> <li>Reviews and approves appropriate clinical documents and manages clinical- investigator relationship/interactions.</li> </ul>
4	N/A	

# Technical Management

Level	Competency	Criteria
1	Collects and organizes information on regulatory requirements for quality, preclinical, and clinical data to meet regulations, standards, and guidelines.	<ul style="list-style-type: none"> <li>• Develops communication skills to foster collaboration.</li> <li>• Understands basic regulations and project requirements.</li> <li>• Conveys clear requirements to cross-functional teams and collects the respective data from stakeholders, e.g., quality, preclinical and clinical functions.</li> <li>• Organizes data to satisfy submission-specific required information.</li> </ul>
2	Assesses the acceptability of objective evidence and documentation for submission filing to comply with applicable regulations, standards, and guidelines.	<ul style="list-style-type: none"> <li>• Understands data used to support regulatory submissions.</li> <li>• Evaluates data to verify submission filing is in compliance with regulatory requirements.</li> </ul>
3	Evaluates proposed changes for regulatory filing solutions and proposes plans for changes that do not require submissions.	<ul style="list-style-type: none"> <li>• Evaluates data and guides cross-functional teams for proposed changes and impact.</li> <li>• Reviews changes for regulatory impact and provides recommendation</li> </ul>
4	N/A	

# Postapproval/Postmarket Domain

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

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

## Adverse Event Management

Level	Competency	Criteria
1	Manage systems to trigger and log regulatory reporting and to track, manage and report product-associated events.	<ul style="list-style-type: none"> <li>Understands the regulatory requirements for adverse-event (AE) reporting.</li> <li>Manages AE reporting and reports AEs, per regulatory requirements.</li> <li>Helps and/or develops investigation and analysis, summary reports, and communications.</li> <li>Provides input in developing AE management systems.</li> <li>Maintains logs that support trending and analysis for both calls and formal vigilance reports.</li> </ul>
	Provides regulatory input and support and as necessary follow-up for inspections and audits.	<ul style="list-style-type: none"> <li>Supports planning and preparing for inspections and audits.</li> <li>Supports leadership in post-audit analysis and corrective action.</li> </ul>
2	Notifies organization and as necessary regulatory authorities as required regarding product safety issues to ensure compliance with local, regional, and global regulations.	<ul style="list-style-type: none"> <li>Reviews and evaluates product-related safety and assesses the regulatory effect of proposed resolutions.</li> <li>Informs cross-functional stakeholders and management about safety issues and regulatory action plans.</li> <li>Notifies local, regional, and global regulatory authorities about product-related safety, per regulatory requirements.</li> <li>Submits follow-up reports to regulatory authorities, when required.</li> </ul>
3	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.	<ul style="list-style-type: none"> <li>Obtains and maintains accurate knowledge of country-/region-specific AE reporting requirements.</li> <li>Develops processes and systems to track, manage, report, and communicate product-associated complaints, recalls, market withdrawals, vigilance, and implementation, including unexpected AEs arising from clinical trials; incorporates AE and pharmacovigilance information into annual reports, as required.</li> <li>Verifies processes to manage reporting; reviews recalls to ensure they are maintained and updated, per evolving regulations.</li> <li>Communicates with regulatory authorities to ensure any required follow-up/post-market surveillance commitments are met following a product-related safety event.</li> <li>Establishes and maintains systems for the regular and consistent analysis of calls, AEs, and complaints.</li> </ul>

\*This knowledge area has been eliminated.

Level	Competency	Criteria
3	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.	<ul style="list-style-type: none"> <li>• Reviews inputs from cross-functional partners on topics, such as reimbursement, to develop and adapt post-market strategy.</li> <li>• Participates in preparation of post-market strategy with cross-functional partners, ensuring both regulatory compliance and business goals are met.</li> </ul>
4	Leads and represents the regulatory team in product associated events, recalls and product withdrawals.	<ul style="list-style-type: none"> <li>• Develops short-term and long-term regulatory strategies to handle post-marketing crises, such as recalls, and other AEs. <ul style="list-style-type: none"> <li>– Short-term: Ensures immediate containment actions are taken to mitigate the event(s).</li> <li>– Long-term: Works with partners in quality to ensure that product(s) and associated documentation return to a state of regulatory compliance.</li> </ul> </li> <li>• Ensures regulatory strategies deployed during crises are aligned with regulatory compliance and business needs.</li> <li>• Ensures an appropriate system is available and followed to track, manage, report, and communicate product-associated complaints, recalls, market withdrawals, and vigilance reports, both internally and externally.</li> <li>• Provides decisions based on the data for product recall and withdrawals in compliance with regulatory requirements.</li> </ul>

## Change Management

Level	Competency	Criteria
1	Monitors and participates in the review of change requests to ensure compliance and the potential for regulatory submissions.	<ul style="list-style-type: none"> <li>• Provides regulatory assessments to support minor changes both pre- and post-approval.</li> <li>• Works with the regulatory function when the team is faced with complex changes or uncertain approaches proposed by the organization.</li> <li>• Works with the functions that are proposing changes to explain potential regulatory effects.</li> </ul>
2	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.	<ul style="list-style-type: none"> <li>• For minor changes, compiles necessary change-notification submissions to the appropriate agency/notified bodies.</li> <li>• Communicates internally and externally according to a formal plan or SOP.</li> </ul>
3	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.	<ul style="list-style-type: none"> <li>• Provides regulatory assessment to support moderate to complex preapproval and post-approval changes for potential effects on business objectives, and communicates that accordingly.</li> <li>• Provides assessments that address domestic and global requirements.</li> <li>• Trains regulatory team to develop its assessment skills for complex changes or uncertain approaches proposed by the organization.</li> </ul>
4	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.	<ul style="list-style-type: none"> <li>• Ensures others in the organization are aware of external requirements that affect business objectives or approval/ clearance timing.</li> <li>• Uses regulatory intelligence to predict changes in the regulatory landscape, communicates that intelligence, and incorporates it into team/project strategy and organizational policies.</li> </ul>

## Recordkeeping

Level	Competency	Criteria
1	Monitors regulatory input and approval to advertising and promotion materials and activities to ensure regulatory compliance.	<ul style="list-style-type: none"> <li>Understands advertising and promotional regulatory requirements.</li> <li>Monitor statutes, regulations, and guidance, communicating changes to management.</li> </ul>
2	Reviews and recommends advertising and promotion to ensure regulatory compliance.	<ul style="list-style-type: none"> <li>Proposes wording for advertising and promotional material for management review.</li> </ul>
3	Develops, implements and manages systems to track required reports, supplemental submissions and other post-marketing commitments.	<ul style="list-style-type: none"> <li>Establishes systems for tracking all reporting requirements, submissions, post-marketing requirements and commitments, and completed reviews.</li> <li>Delegates day-to-day operations to staff while providing oversight.</li> </ul>
4	N/A	

## Recordkeeping and Monitoring

Level	Competency	Criteria
1	Performs data input.	<ul style="list-style-type: none"> <li>Collects regulatory data items and inputs data using appropriate systems per company's processes while ensuring regulatory compliance. Sorts data appropriately with high attention to detail.</li> <li>Reviews data for errors and corrects where necessary.</li> <li>Generates reports and/or metrics while meeting deadlines.</li> <li>Learns the practice of identifying and communicating possible data trends.</li> </ul>
2	Develops and implements processes involved with maintaining annual licenses, registrations, and listings.	<ul style="list-style-type: none"> <li>Researches annual licensing, registration, and listing requirements.</li> <li>Develops/maintains annual licensing, registration, and listing processes.</li> <li>Ensures both regulatory compliance needs and business needs are met.</li> <li>Ensures that annual licensing, registration, and listing processes are regularly reviewed and updated to account for regulatory changes.</li> </ul>
3	Ensures process is in place for review and approval of advertising and promotion to ensure regulatory compliance.	<ul style="list-style-type: none"> <li>Develops/maintains regulatory review process for advertising and promotion to ensure claims intended for publicly disseminated information (press releases, website, marketing/promotional material) are reviewed by subject matter experts (SMEs) in regulatory affairs.</li> <li>Proposes appropriate software solutions to manage marketing materials for regulatory review and to support historical access and analysis.</li> <li>Coaches junior team members on how to review ad/promo material to ensure claims made are compliant per applicable regulations.</li> <li>Ensures ad/promos reviews are documented and communicated to appropriate stakeholders.</li> </ul>

Level	Competency	Criteria
4	Reviews and approves enforcement action/responses.	<ul style="list-style-type: none"> <li>• Collaborates with quality assurance to review proposed enforcement actions/responses, with particular attention to maintaining regulatory compliance.</li> <li>• Communicates with and responds to regulatory authorities regarding any required follow-ups to enforcement actions/responses are met.</li> </ul>

## Record Keeping and Product Management

Level	Competency	Criteria
1	Tracks and maintains files on annual licenses, registrations, and listings.	<ul style="list-style-type: none"> <li>• Supports/manages applicable regulatory licenses, registrations, and listings in an organized manner with an emphasis on deadlines and planning.</li> </ul>
2	Assures postmarket regulatory requirements are met (e.g., required reports, supplemental submissions and other postmarketing commitments).	<ul style="list-style-type: none"> <li>• Supports/manages post-market activities to ensure regulatory activities are compliant.</li> <li>• Develops post-market strategies to ensure effective solutions for solutions for commitments and change management.</li> </ul>
3	Reviews and approves required reports, supplemental submissions and other post marketing commitments to maintain product registrations.	<ul style="list-style-type: none"> <li>• Leads post-market regulatory strategies, ensures compliance to commitments, and incorporates change management into these activities.</li> <li>• Leads agency interactions to negotiate commitments and meetings to discuss supplemental submissions.</li> <li>• Maintains a keen awareness about deadlines and the planning required to meet those deadlines.</li> </ul>
4	N/A	

# Business Acumen Domain

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

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

## Continuous Improvement

Level	Competency	Criteria
1	Participates in and supports continuous-improvement processes as identified by the organization.	<ul style="list-style-type: none"> <li>Supports leadership in organizational initiatives, participates in training, and assists with tracking progress and outcomes.</li> </ul>
2	Continually improves the quality of policies, programs and services provided.	<ul style="list-style-type: none"> <li>Looks for opportunities where continuous improvement is needed and provides recommendations for change.</li> </ul>
3	Leads integrated regulatory process and system-improvement initiatives that influence and build new capabilities for greater effectiveness and efficiencies.	<ul style="list-style-type: none"> <li>Sponsors and leads specific improvement projects, ensures appropriate resources are available for projects, and provides continuous training to resources.</li> <li>Secures participation and buy-in from other organizational stakeholders.</li> </ul>
4	Assesses the data/ metrics/ performance etc., generated for continuous-improvement opportunities within the organization and leverages such information to achieve regulatory objectives.	<ul style="list-style-type: none"> <li>Identifies and recommends strategic areas for continuous-improvement activities.</li> <li>Ensures appropriate training processes are in place to support activities and ensures processes are standardized across the regulatory function.</li> <li>Uses data metrics to improve processes and long-term planning.</li> <li>Aligns continuous-improvement progress with overall organizational strategy.</li> </ul>

## Industry-Specific Knowledge

Level	Competency	Criteria
1	Identifies data that may be indicative of future trends that can be used to improve policies and procedures.	<ul style="list-style-type: none"> <li>Learns own role, departmental business goals, and company.</li> </ul>
2	Frames issues with a thorough understanding of legislation, regulations, guidance, policy, and directives.	<ul style="list-style-type: none"> <li>Monitors and communicates relevant and updated information to department, cross-functional teams, and collaborators.</li> </ul>

Level	Competency	Criteria
3	Represents the organization with a thorough understanding of and ability to communicate about legislation, regulation, guidance, policy, and directives.	<ul style="list-style-type: none"> <li>Leads strategy based on knowledge of past and current regulatory trends, anticipating potential trends in the future.</li> </ul>
4	Communicates regulatory and scientific issues with management, ensuring that management understands the regulatory and scientific challenges.	<ul style="list-style-type: none"> <li>Liaises with and advises leadership team and stakeholders on issues with current and future impact.</li> </ul>
	Provides recommendations to decision makers on regulatory strategies and options on new products or claims that balance business needs with regulatory oversight.	<ul style="list-style-type: none"> <li>Ensures active communication across organization and with stakeholders in presenting regulatory strategy in context of business perspective.</li> </ul>
	Interprets and translates regulatory requirements into business opportunities.	<ul style="list-style-type: none"> <li>Monitors and communicates trends with business groups to position organization for business success.</li> </ul>
	Supports due diligence processes for the organization by ensuring effective regulatory assessment.	<ul style="list-style-type: none"> <li>Leads regulatory due diligence evaluation.</li> </ul>

## Operational Knowledge

Level	Competency	Criteria
1	Preserves confidentiality of product information, as appropriate.	<ul style="list-style-type: none"> <li>Works on projects while maintaining confidentiality and managing sensitive content.</li> <li>Understands differences between confidential and non-confidential content.</li> <li>Completes required training and adheres to organization's privacy policies.</li> </ul>
2	Maintains knowledge of evolving regulatory information systems and makes recommendations regarding potential application within the organization.	<ul style="list-style-type: none"> <li>Recognizes and communicates when new regulatory system changes can be used to facilitate business objectives.</li> </ul>
	Understands financial information used to make department/unit and organization-wide decisions and assists in the development and monitoring of department/unit budgets.	<ul style="list-style-type: none"> <li>Maintains awareness of individual responsibility for the financial health of the organization.</li> </ul>
3	Uses financial analysis to generate, evaluate and act on strategic options and opportunities to support business decisions and manage and develop budgets.	<ul style="list-style-type: none"> <li>Understands business concepts, such as revenue, market share, and earnings before interest, taxes, depreciation, and amortization.</li> <li>Collaborates with the finance department to understand applicable financial information about the company.</li> </ul>
	Performs and/or supervises regulatory due diligence and identifies risks and opportunities for executive management (such as M&A).	<ul style="list-style-type: none"> <li>Selects, assigns, supervises, and coaches individuals who perform due diligence.</li> <li>Educates executive management on due diligence process and best practices.</li> <li>Creates and drives due diligence process for all potential situations requiring due diligence, including mergers and acquisitions .</li> <li>Helps identify specific areas where confidentiality is necessary (e.g., personnel impact, redundancies) and communicates with senior management.</li> </ul>

Level	Competency	Criteria
4	Creates a culture of good information practices, protection/safeguarding of information.	<ul style="list-style-type: none"> <li>Communicates expectations to the regulatory function regarding the importance of handling sensitive information.</li> <li>Provides education to the company on handling sensitive regulatory information.</li> <li>Leverages legal resources within the organization to align with organizational standards.</li> </ul>
	Understands and utilizes financial information to contribute to organizational business decisions and to make regulatory business-unit decisions.	<ul style="list-style-type: none"> <li>Creates and justifies regulatory department budget to align with company financial status and regulatory resourcing needs.</li> <li>Incorporates applicable financial status and constraints into regulatory strategy to prepare for presentation to executive management.</li> </ul>
	Analyzes due diligence process for company sales, acquisitions, and mergers.	<ul style="list-style-type: none"> <li>Monitors and continuously improves the due diligence process, incorporating lessons learned from previous situations.</li> </ul>

## Operational Knowledge and Project Management

Level	Competency	Criteria
1	Develops/expands project management capabilities, as needed.	<ul style="list-style-type: none"> <li>Determines submission and approval requirements and plans to compile, prepare, review, and submit regulatory submission to authorities within specified timeframes.</li> <li>Tracks and reports status of regulatory actions to appropriate stakeholders.</li> </ul>
	Tracks the staging of activities and milestones in regulatory work plans.	<ul style="list-style-type: none"> <li>Communicates roadblocks in a timely manner to upline supervisor/manager.</li> <li>Proactively identifies potential pathways and solutions to issues and roadblocks.</li> <li>Establishes clear communication and proactive follow-up with health authority to facilitate reviews and ensure submissions are approved within targeted timeframes.</li> </ul>
2	Identifies key resources and personnel for the project team—internal and external to their direct area of responsibility.	<ul style="list-style-type: none"> <li>Identifies internal and external stakeholders for effective communication regarding plans, roadblocks, and review/approval timeframes.</li> <li>Takes ownership and leads end-to-end planning, coordination, and execution of assigned deliverables.</li> </ul>
	Creates work plans with appropriate staging of activities and with clearly defined milestones that match the organization's strategic objectives.	<ul style="list-style-type: none"> <li>Identifies regulatory deliverables and creates work plans with clearly defined milestones.</li> <li>Collaborates with business functions to develop mitigation strategies and address roadblocks.</li> <li>Communicates project status to stakeholders in a timely manner.</li> </ul>

Level	Competency	Criteria
3	Assesses and approves work plans to ensure appropriate staging of activities and with clearly defined milestones.	<ul style="list-style-type: none"> <li>• Develops and maintains project plans for regulatory activities across product portfolios.</li> <li>• Based on project plans, anticipates regulatory obstacles and emerging issues throughout the product lifecycle and develops solutions with other regulatory team members and cross-functional teams.</li> <li>• Holds team members accountable for assigned tasks and deliverables.</li> <li>• Creates departmental reports to track against established metrics.</li> <li>• Encourages best practices for project management within the department.</li> </ul>
4	Provides strategic guidance for resource and development planning.	<ul style="list-style-type: none"> <li>• Identifies metrics for project success within regulatory.</li> <li>• Implements training for department staff on project management and regulatory operations.</li> </ul>
	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.	<ul style="list-style-type: none"> <li>• Develops a project management framework for the regulatory department at each skill level.</li> <li>• Based on regulatory department output volume, identifies and implements appropriate project management tools for department use.</li> <li>• Fosters an open, collaborative environment encouraging staff to say when targets cannot be achieved.</li> <li>• Creates processes, structures, roles, and metrics to ensure strategic objectives are met.</li> </ul>

## Quality Management

Level	Competency	Criteria
1	N/A	
2	N/A	
3	Integrates qualitative and quantitative information to draw accurate conclusions.	<ul style="list-style-type: none"> <li>• Observes and participates as quality procedures are followed to support regulatory processes and provides appropriate guidance.</li> </ul>
	Evaluates corporate policies to mitigate regulatory risk to ensure adequate compliance to help the company achieve its business goals.	<ul style="list-style-type: none"> <li>• Ensures quality policies and procedures meet regulatory requirements and when inadequate, communicates discrepancies.</li> </ul>
4	Anticipates challenges, develops strategies and assures implementation to resolve complex issues with potential for significant regulatory impact.	<ul style="list-style-type: none"> <li>• Provides support and guidance to the development, implementation, and revision of quality systems to maintain compliance.</li> </ul>
	Oversees regulatory aspects of business relationships to ensure compliance and protect corporate interests.	<ul style="list-style-type: none"> <li>• Provides strategic regulatory assessment of potential quality system and quality compliance issues.</li> </ul>

# Scientific and Health Concepts Domain

Description: Understanding evolving regulatory science and applying it to improve the development, review, and oversight of healthcare products

Knowledge Areas: Knowledge Areas: Regulatory Knowledge\*, Application of Scientific and Clinical Advances, Healthcare Leadership, Quality Management\*\*

## Application of Scientific and Clinical Advances

Level	Competency	Criteria
1	Tracks scientific and/or clinical advances impacting healthcare product development and regulations.	<ul style="list-style-type: none"> <li>• Uses resources and competent authority websites to stay abreast of intelligence in the disease space.</li> </ul>
	Engages in continuous learning activities to maintain technical competence in the product areas supported.	<ul style="list-style-type: none"> <li>• Attends webinars, internal training, and industry conferences for relevant disease space /healthcare awareness and intelligence.</li> </ul>
2	Assesses the scientific and/or clinical advances impacting healthcare product development and regulation.	<ul style="list-style-type: none"> <li>• Identifies areas to apply scientific knowledge and advancements.</li> </ul>
	Participates in targeted education, clinical science , and evolving-science study to meet regulatory requirements for emerging technologies.	<ul style="list-style-type: none"> <li>• Leads, trains, and coaches junior-level staff to better understand the disease space and encourages collaboration with other groups across the organization.</li> </ul>
3	Manages or leads the process that monitors updates on scientific and clinical advances impacting healthcare product development and assesses the relationship to regulation and regulatory issues.	<ul style="list-style-type: none"> <li>• Participates in round table discussions with other groups to determine potential changes required in the disease space.</li> </ul>
	Interprets evolving global regulatory science to develop new approaches to improve the development, review, and oversight of healthcare products.	<ul style="list-style-type: none"> <li>• Proposes updated ways of working to align with industry practices in a specific disease space or with competent authority feedback for the therapeutic area.</li> </ul>
4	Identifies and proactively responds to scientific and/or clinical advances impacting healthcare product development and regulations.	<ul style="list-style-type: none"> <li>• Collaborates with senior leadership to drive consensus and consistent internal standards within the organization based on industry benchmarks.</li> </ul>
	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.	<ul style="list-style-type: none"> <li>• Strategizes with other disciplines within the organization to apply regulatory frameworks in a specific disease space.</li> </ul>

\*This knowledge area has been eliminated.

\*\*This knowledge area has been added.

## Quality Management

Level	Competency	Criteria
1	N/A	
2	Participates in stakeholder groups to help shape science-based regulatory decision making.	<ul style="list-style-type: none"> <li>Participates in cross-function group meetings and provides regulatory guidance to teams to take appropriate regulatory decisions.</li> </ul>
3	Actively engages with stakeholder groups to help shape science based regulatory decision making.	<ul style="list-style-type: none"> <li>Routinely engages with stakeholders and provides feedback and solutions to take science-based regulatory decisions.</li> </ul>
4	Initiates and sponsors stakeholder groups to help shape science based regulatory decision making.	<ul style="list-style-type: none"> <li>Prepares regulatory strategies and arranges meetings with stakeholders to shape science-based regulatory decisions and defines the regulatory pathways.</li> </ul>

## Healthcare Leadership

Level	Competency	Criteria
1	N/A	
2	Participates in stakeholder groups to help shape science-based regulatory decision making.	<ul style="list-style-type: none"> <li>Participates in cross-function group meetings and provides regulatory guidance to teams to take appropriate regulatory decisions.</li> </ul>
3	Actively engages with stakeholder groups to help shape science based regulatory decision making.	<ul style="list-style-type: none"> <li>Routinely engages with stakeholders and provides feedback and solutions to take science-based regulatory decisions.</li> </ul>
4	Initiates and sponsors stakeholder groups to help shape science based regulatory decision making.	<ul style="list-style-type: none"> <li>Prepares regulatory strategies and arranges meetings with stakeholders to shape science-based regulatory decisions and defines the regulatory pathways.</li> </ul>

# Ethics Domain

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

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

## Ethical Behaviors

Level	Competency	Criteria
1	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.	<ul style="list-style-type: none"> <li>• Reads/trains on ethics policies and procedures and understands individual roles in both personal compliance, reminding others of this responsibility as necessary.</li> <li>• Remains fair and objective and raises concerns through appropriate organizational channels.</li> </ul>
2	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.	<ul style="list-style-type: none"> <li>• Identifies unethical behavior or practices per organizational ethics policies and procedures.</li> <li>• Communicates openly and honestly any potential products reliability and quality issues, unfulfilled standards, and regulations compliance concerns.</li> <li>• Communicates issues with confidence.</li> <li>• Understands and abides by RAPS Code of Ethics.</li> </ul>
3	Seeks to ensure ethical behavior by ensuring integrity in personal and organizational practices; respects people and principles including professional, ethical and human values.	<ul style="list-style-type: none"> <li>• Models, coaches, and mentors peers and stakeholders regarding ethical behaviors and practices within the regulatory function and the broader organization.</li> </ul>
4	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.	<ul style="list-style-type: none"> <li>• Models and promotes a climate of openness and honesty, encourages responsible dissent and varied interpretations of regulations.</li> <li>• Does not acquiesce to pressure, works to ensure integrity in personal, and organizational practices.</li> <li>• Creates a process to facilitate raising of concerns through appropriate organizational channels</li> </ul>
	Ensures allocation of resources to enable ethical behaviors across the function and organization, as appropriate.	<ul style="list-style-type: none"> <li>• Reviews team workload/budget in relation to additional products, either through internal development or acquisitions/partnerships.</li> <li>• Coordinates across the organization to enable support of additional future indications or increased sales focus in existing product areas or new geographic regions. Additionally, works to promote and participates in regular product rationalization strategies/reviews.</li> <li>• Uses regulatory metrics to gauge adequate support based on turnaround times, number of review cycles, year over year increase of document reviews (e.g., for ad promo pieces, quality documentation, on time approvals/clearances) to adequately support business needs.</li> <li>• Employs competency assessment to ensure the right skills for key roles.</li> </ul>

## Legal and Regulatory Requirements

Level	Competency	Criteria
1	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.	<ul style="list-style-type: none"> <li>Identifies the applicable authorities under which the organization operates.</li> <li>Reviews the applicable laws and regulations of the authorities.</li> <li>Internally proposes new policies and directives or proposes revisions of existing policies and directives to adhere to the laws and regulations.</li> <li>Completes timely formal training.</li> </ul>
2	"See footnote"	
3	"See footnote"	
4	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.	<ul style="list-style-type: none"> <li>Defines, communicates, and implements fundamental principles of regulatory compliance, competency, objectivity, integrity, honesty/credibility, accountability, fairness, dignity, and respect into training and evaluations of self, organizations, and industry.</li> </ul>

## Recognizing and Resolving Unethical Behavior

Level	Competency	Criteria
1	Aware of potential for conflicts of interest between work responsibilities and private affairs.	<ul style="list-style-type: none"> <li>Assists in researching, identifying, and assessing the potential for conflicts of interest.</li> </ul>
	Raises and escalates, as appropriate, potential organizational ethics and compliance issues.	<ul style="list-style-type: none"> <li>Assists in researching organizational codes of ethics and compliance codes (specific to the industry/products).</li> <li>Trains on organizational ethics and compliance policies.</li> <li>Uses organizational processes for reporting potential ethics and compliance issues.</li> </ul>
2	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.	<ul style="list-style-type: none"> <li>Communicates and follows the conflict-of-interest policy and provides regular reminders as necessary.</li> <li>Supports the communication of up-to-date information about the organization's policy, rules, and procedures.</li> <li>Identifies preventive measures dealing with emergency conflict situations.</li> <li>Develops an open organizational culture where dealing with conflict-of-interest matters can be freely raised and discussed.</li> <li>Establishes relevant facts, applies the relevant law and policy, distinguishes between real, apparent, and potential conflict situations, and understands the many issues which are involved.</li> </ul>

\*Levels 2 and 3 are expected to know and apply Legal and Regulatory requirements just as in Level 1

Level	Competency	Criteria
3	Coaches and mentors others to help them recognize potential organizational ethics and compliance issues.	<ul style="list-style-type: none"> <li>Identifies and communicates any additional requirements relevant to the organization.</li> </ul>
	Raises and escalates, as appropriate, significant organizational ethics and compliance issues.	<ul style="list-style-type: none"> <li>Trains on ethics policy and models it in daily business.</li> <li>Initiates regular contact with colleagues to capture ethical and compliance issues.</li> <li>Captures potential ethical compliance issues and escalates as appropriate.</li> <li>Mentors others on ethical and compliance issues.</li> <li>Prevents ethical and compliance issues, (e.g., based on experiences).</li> <li>Develops an open organizational culture where dealing with conflict-of-interest matters can be freely raised and discussed.</li> </ul>
4	Evaluates to assure compliance with conflict of-interest guidelines and adherence with FCPA and other legislation directed at fraud and corruption.	<ul style="list-style-type: none"> <li>Ensures organization's current policies, procedures, and actions are consistent with legal and governmental regulatory ethical requirements.</li> </ul>

# Leadership Domain

Description: 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 Areas: Leadership, Talent Management, Negotiation, Conflict Management, Collaboration, Communication, Relationship Management

## Collaboration

Level	Competency	Criteria
1	Demonstrates and advocates for working together in the spirit of openness, honesty, and transparency that encourages engagement, collaboration, respectful interactions, and trust.	<ul style="list-style-type: none"> <li>Builds trust with both internal and external stakeholders through clear communication and collaboration.</li> <li>Collaborates with cross-functional teams and key stakeholders, ensuring completion of assigned tasks.</li> <li>Fosters trust within the organization by empowering through example.</li> <li>Proactively communicates impact of applicable regulatory changes to stakeholders in a timely manner.</li> </ul>
	Seeks out diverse ideas, opinions and insights, and applies them in the workplace.	<ul style="list-style-type: none"> <li>Attends diversity, equity, and inclusion programs to increase awareness.</li> <li>Maintains awareness of diversity issues within the workgroup and incorporates them into action plans.</li> <li>Considers varying interpretations of the regulations and seeks to reach consensus on methods/strategy for completing regulatory-related projects or tasks.</li> <li>Supports a workplace environment which encourages and gives voice to a wide range of thoughts, opinions, and skill sets.</li> </ul>
2	Provides guidance and support to keep teams and the organization focused on objectives.	<ul style="list-style-type: none"> <li>Suggests improvements to departmental processes and procedures to promote collaboration and ensure clear, repeatable outcomes.</li> <li>Identifies improvement opportunities in regulatory affairs processes while developing and proposing solutions.</li> <li>Freely shares information and offers guidance to team members.</li> <li>Understands the alignment of individual objectives, organizational objectives, and corporate objectives for overall success.</li> <li>Understands priorities and progress points to achieve objectives.</li> </ul>
	Contributes to building a respectful, diverse, and inclusive workplace where decisions and transactions are transparent and fair.	<ul style="list-style-type: none"> <li>Adheres to policies, goals, objectives, and philosophies that value diversity in performing duties and responsibilities.</li> <li>Builds teams by recognizing and leveraging skills of stakeholders with diverse backgrounds to benefit the organization, clients, and coworkers.</li> <li>Educates self and stakeholders regarding appropriate use of inclusive language to address bias and promote diversity.</li> <li>Uses transparent structures for promotions, raises, and stretch assignments to ensure equity.</li> </ul>

Level	Competency	Criteria
3	N/A	
4	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.	<ul style="list-style-type: none"> <li>Creates a diverse and inclusive environment connecting different cultures, ideas, and experiences.</li> <li>Identifies creative approaches for targeted recruiting and promotion to develop a representative workforce that benefits from diverse strengths.</li> <li>Collaborates with senior leaders to define and model different aspects of diversity, equity, and inclusion, and a respectful and fair work environment within the organization.</li> <li>Identifies potential leaders who will promote an inclusive and respectful work environment.</li> <li>Supports the development of policies and procedures to promote an inclusive and respectful work environment.</li> </ul>

## Communication

Level	Competency	Criteria
1	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.	<ul style="list-style-type: none"> <li>Listens actively to staff ideas and concerns regarding work-related issues.</li> <li>Participates in ongoing training and evaluation aimed at raising awareness about implicit bias and its effect.</li> </ul>
	Clearly conveys information to peers, supervisors and other stakeholders.	<ul style="list-style-type: none"> <li>Updates supervisors on project status and requests support to balance workload, as required.</li> </ul>
	Communicates with knowledge, consistency and clarity to maintain integrity and impact of the message.	<ul style="list-style-type: none"> <li>Provides clear, concise status updates to management at regular intervals.</li> </ul>
2	N/A	
3	Aligns resources and discusses regulatory issues with supervisors and other relevant staff.	<ul style="list-style-type: none"> <li>Communicates with stakeholders regarding necessary actions and suggested approaches to accomplish group objectives.</li> <li>Communicates organizational goals and initiatives to staff in a clear and concise manner.</li> </ul>
	Communicates with peers and supervisors and ensures alignment on issues, questions, and goals.	<ul style="list-style-type: none"> <li>Conveys information clearly and concisely to ensure that staff/ team members remain focused on agenda items.</li> <li>Presents information, analyses, and recommendations to officials and stakeholders.</li> </ul>
	Chooses the best alternative to achieve desired outcome or effect, giving consideration to risks, trade offs, timing and available resources.	<ul style="list-style-type: none"> <li>Uses practical examples, charts, and checklists, to inform risk-based decision making.</li> <li>Practices consistent and effective communication at all steps of the decision-making processes.</li> <li>Explain benefits to stakeholders to gain acceptance of programmatic change.</li> </ul>
4	Develops and implements effective communication and engagement strategies with partners.	<ul style="list-style-type: none"> <li>Conducts presentations and briefings for high-level agency officials.</li> <li>Presents, explains, and defends external regulatory positions and proposals to staff and stakeholders.</li> </ul>
	Communicates updates to staff to gain alignment.	<ul style="list-style-type: none"> <li>Communicates effectively with staff by conducting regular meetings to discuss initiatives and current events .</li> </ul>
	Champions and cultivates a diverse workforce.	<ul style="list-style-type: none"> <li>Builds a diverse team with varied skills that functions effectively to accomplish the organization's mission.</li> </ul>
	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.	<ul style="list-style-type: none"> <li>Communicates sensitive information with broad organizational repercussions.</li> </ul>

# Conflict Management and Negotiation

Level	Competency	Criteria
1	Creates clarity and direction amid complexity and develops solutions for self, colleagues, and the organization.	<ul style="list-style-type: none"> <li>Reviews and clearly summarizes information.</li> <li>Distributes findings to colleagues and organization with appropriate oversight.</li> <li>Meets one-on-one with team members to resolve issues.</li> <li>Seeks guidance on approaches to resolve issues.</li> <li>Raises grievances to management in accordance with institutional processes.</li> </ul>
2	Navigates the dynamics, alliances, and competing requirements of the organization or business by providing solid rationale to support recommendations and decisions.	<ul style="list-style-type: none"> <li>Reviews organizational requirements.</li> <li>Understands the competing requirements of the organization.</li> <li>Proposes solutions to acknowledge competing requirements and uphold regulatory requirements.</li> <li>Uses employee concerns to propose changes to ensure that the work environment is fair and equitable.</li> <li>Ensures employees receive coaching, mentoring, and mediation to resolve issues affecting the workgroup.</li> <li>Realizes emotional intelligence of self and others.</li> </ul>
3	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.	<ul style="list-style-type: none"> <li>Meets with employees within workgroups and addresses concerns in an open and honest manner.</li> <li>Takes action to address behavioral issues to ensure employees treat each other with respect.</li> <li>Manages conflict among team members by utilizing mediation techniques.</li> </ul>
4	Makes tough or unpopular decisions where mission outcomes supersede the interests/concerns of individuals, constituencies or current situation.	<ul style="list-style-type: none"> <li>Proactively recognizes potential conflicts and addresses issues by meeting with the involved parties.</li> <li>Mitigates staff concerns regarding issues at the organizational level by investigating allegations and taking appropriate action.</li> </ul>

# Leadership

Level	Competency	Criteria
1	Demonstrates composure and receptivity when presented with feedback and uses feedback as an opportunity to learn and improve.	<ul style="list-style-type: none"> <li>Understands and applies the concept of emotional intelligence.</li> <li>Meets with staff and supervisors to discuss opportunities and challenges.</li> <li>Accepts constructive feedback and asks questions that foster a professional-growth mindset.</li> <li>Accepts own mistakes and participate in lessons-learned events.</li> </ul>
	Connects and relates well with people who think and act differently than oneself.	<ul style="list-style-type: none"> <li>Communicates organizational or unit vision to other staff and stakeholders.</li> <li>Understands and accepts other perspectives and viewpoints.</li> </ul>
2	Willingly accepts challenging assignments and new career opportunities that stretch and build capabilities.	<ul style="list-style-type: none"> <li>Identifies opportunities to promote the organization's or unit's vision to the team.</li> </ul>

Level	Competency	Criteria
3	Articulates the organization's strategic vision in a manner that enables others to execute plans, tactics and actions.	<ul style="list-style-type: none"> <li>• Synthesizes complex information gathered from a variety of external sources and disseminates it to staff.</li> <li>• Involves employees and stakeholders in an organizational change process by conducting meetings and providing frequent updates.</li> <li>• Communicates vision and mission of organization to employees while incorporating employee feedback on accomplishing new goals and objectives.</li> <li>• Educates colleagues and team members about new regulatory strategy and outlines how long-term benefits align with organizational goals.</li> </ul>
	Models humility by readily taking responsibility for errors, acknowledging opportunities for improvement, pursuing new ideas and perspectives, and applying learning.	<ul style="list-style-type: none"> <li>• Leads others through a consensus process on organization's response to controversial issues.</li> <li>• Resolves conflicts arising at the organizational or divisional levels stemming from competing objectives, limited resources, or differing perspectives.</li> <li>• Leads by example, accepts one's own mistakes, and leads lessons-learned events.</li> </ul>
	Continually identifies and informs appropriate individuals on emerging trends, opportunities, and threats.	<ul style="list-style-type: none"> <li>• Anticipates change and establishes a vision to effect change through the formulation and implementation of objectives and priorities.</li> <li>• Designs approaches and procedures to develop strategic plans supporting key organizational goals and objectives.</li> <li>• Performs environmental scanning on a regular basis and translates information into insights and opportunities for the organization.</li> </ul>
4	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.	<ul style="list-style-type: none"> <li>• Considers various viewpoints from internal and external sources when developing a new organizational mission and vision.</li> <li>• Directs and provides guidance to managers to develop long-term strategic plans for the division.</li> <li>• Leads and directs strategic planning teams to address and outline the organization's or division's direction.</li> <li>• Clarifies priorities and adjusts resources to align with organizational priorities.</li> </ul>
	Monitors potential situations or incidents that may compromise individuals, the regulatory function, or organization, and intervenes in a positive manner to resolve the issue.	<ul style="list-style-type: none"> <li>• Acknowledges organizational strengths and develops plans to address areas needing improvement.</li> <li>• Conducts interviews with staff to ascertain organization's needs and if and what action is required.</li> </ul>
	Builds and sustains partnership across organizational boundaries and functions as well as outside the organization to achieve common goals and outcomes.	<ul style="list-style-type: none"> <li>• Builds coalitions to develop and garner support for shared programs.</li> <li>• Develops and implements organizational or divisional initiatives by building coalitions.</li> </ul>

## Negotiation

Level	Competency	Criteria
1	N/A	
2	N/A	
3	Makes informed decisions based on business frameworks and tools and gives consideration to risks, trade offs, timing, and available resources.	<ul style="list-style-type: none"> <li>• Develops trust among negotiating parties.</li> <li>• Supports management to provide alternate approaches to complex situations.</li> <li>• Represents the organization in reaching agreements with other organizations, such as health authorities, industry members, and notified bodies.</li> <li>• Mentors junior team members to develop negotiation skills using organizational tools and team-management strategies to gain consensus.</li> </ul>
4	Makes timely and effective decisions, balancing the need for more information or analysis with the need to be decisive.	<ul style="list-style-type: none"> <li>• Influences other leaders regarding changes within the organization or supports/resources needed for the regulatory affairs function.</li> <li>• Represents the organization at a senior level to persuade and reach agreement with other organizations, competent authorities, notified bodies, and industry members.</li> <li>• Works with the regulatory affairs team and others to develop a strategy for senior leadership decision making and risk mitigation.</li> <li>• Steps in when others are unable to reach resolution.</li> <li>• Mentors team members in negotiating, using organizational tools and team-management strategy to gain consensus.</li> </ul>

## Relationship Management

Level	Competency	Criteria
1	N/A	
2	Clearly conveys or exchanges information with stakeholders within and outside the organization in an appropriate and timely manner.	<ul style="list-style-type: none"> <li>• Listens actively to team ideas and concerns and resolves any issues by meeting one-on-one with team members.</li> <li>• Regularly updates managers on project status.</li> <li>• Synthesizes information (e.g., regulations/standards/policies) gathered from a variety of external sources and disseminates to teams/affected parties.</li> <li>• Encourages others to contribute by overcoming cultural barriers and background differences.</li> </ul>

Level	Competency	Criteria
3	Delivers key messages effectively to a wide variety of audiences at all levels.	<ul style="list-style-type: none"> <li>Communicates effectively with staff by conducting regular meetings to discuss regulatory initiatives and projects.</li> <li>Communicates with stakeholders regarding necessary actions and suggested approaches to accomplish objectives.</li> <li>Explains benefits to stakeholders to gain acceptance of regulatory objectives and/or changes.</li> <li>Presents complex information, analyses, and recommendations to officials and stakeholders.</li> <li>Reads cues from various audiences to assess when and how to change the planned communication approach to effectively deliver messages.</li> </ul>
	Organizes, prepares for, and facilitates effective meetings with internal and external stakeholders.	<ul style="list-style-type: none"> <li>Provides status updates on regulatory projects at management team meetings.</li> <li>Conducts presentations and briefings on regulatory news and updates for high-level stakeholders.</li> <li>Resolves conflicts stemming from competing objectives, limited resources, or differing perspectives.</li> <li>Leads managers through consensus process on agency's response to controversial issues.</li> <li>Reviews complex and/or sensitive work and identifies potential impact on the organization.</li> <li>Responds to challenges of internal and external stakeholders quickly.</li> </ul>
4	Communicates the organization's regulatory position to business partners.	<ul style="list-style-type: none"> <li>Presents complex regulatory situations articulately when meeting with key executives or public officials regarding high-visibility and/or complex issues.</li> <li>Communicates sensitive information with broad organizational effect on topics without precedence.</li> <li>Builds business partners' confidence in organization using one's reputation in the international community and expertise.</li> </ul>

## Talent Management

Level	Competency	Criteria
1	Support and mentor direct colleagues in their personal development.	<ul style="list-style-type: none"> <li>Provides developmental feedback to staff on job performance.</li> <li>Involves staff in developing project goals and timelines.</li> <li>Works to self-identify areas for potential improvement.</li> <li>Engages in supportive discussions with peers regarding opportunities for improvement and growth.</li> </ul>
2	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.	<ul style="list-style-type: none"> <li>Encourages employees to participate in mentoring programs and other learning opportunities.</li> <li>Pairs new staff with seasoned employees to facilitate understanding of the position and organization.</li> <li>Provides orientation to new employees.</li> </ul>
	Participates in talent management practices to support the development of a workforce that is well aligned with business needs.	<ul style="list-style-type: none"> <li>Participates in internal development programs, such as career exposure, cross-training, and other formal feedback programs.</li> </ul>

Level	Competency	Criteria
3	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.	<ul style="list-style-type: none"> <li>Assesses staff, providing timely and consistent feedback regarding technical proficiency and effectiveness.</li> <li>Provides constructive feedback, guidance, and reinforcement to employees regarding job performance.</li> <li>Works with staff to identify work goals and create individual development plans.</li> <li>Evaluates training programs to ensure content meets staff needs.</li> </ul>
	Identifies and connects talent needs with talent resources; recruits, retains, manages, and develops regulatory professionals to support the business strategy.	<ul style="list-style-type: none"> <li>Collaborates with human resources and/or talent acquisition to implement recruitment and retention strategies.</li> </ul>
4	Creates challenging tasks and development opportunities for employees within the organization and strives for the importance of personal development.	<ul style="list-style-type: none"> <li>Creates and recommends developmental assignments based on functional capabilities and organizational needs.</li> <li>Works with staff to develop individual development plans and recommends appropriate training to address employee needs and organizational goals.</li> </ul>
	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.	<ul style="list-style-type: none"> <li>Partners with human resources and/or talent acquisition to develop recruitment and retention strategies.</li> <li>Mentors and coaches to support talent management and development within the organization.</li> </ul>

# Acknowledgments

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