

Regulatory Affairs Professional Development Framework

AN OVERVIEW



REGULATORY AFFAIRS
PROFESSIONALS SOCIETY

Making better healthcare products possible

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ABSTRACT

Professions are characterized by several factors, including an identifiable body of knowledge, a pathway for advancing knowledge and skills related to the profession and an emphasis on continued learning and development. This paper presents the Regulatory Affairs Professionals Society (RAPS) Professional Development Framework (PD Framework) for the healthcare product regulatory affairs (RA) profession. The PD Framework offers a model for describing the basic body of knowledge and relevant skills of the RA profession across product lines, geographic locations and employer types at four major career stages. The framework is the result of years of research and development carried out by RAPS with the involvement of members worldwide. The studies' results provide valuable insights into the nature of the profession. The framework defines the profession by professional/career levels, domains that reflect steps in the healthcare product lifecycle, the responsibilities and tasks of the RA professional at each step and the associated core knowledge and skills required of the professional.

INTRODUCTION

Regulatory affairs (RA) professionals play critical roles throughout the healthcare product lifecycle, from concept through product obsolescence. They provide strategic, tactical and operational direction and support for working within regulations to expedite the development and delivery of safe and effective healthcare products to individuals around the world. Continuous evolution in science and changes in the regulatory environment, health sector and general economics shape the dynamic and expanding scope of the regulatory affairs professional. RA professionals must continually grow their knowledge and skills to be effective and to advance in their profession.

The Regulatory Affairs Professionals Society (RAPS) was established in 1976 with a mission of creating the foundation for developing and nurturing the emerging healthcare product regulatory affairs profession. A key building block of establishing RA as a profession was put into place in 1990 when RAPS introduced a professional certification, the Regulatory Affairs Certification (RAC). The development of the RAC was based upon extensive research on the scope of practice and specific activities of the professional with three to five years of regulatory experience, the target for this professional credential. This research has been replicated and updated several times, with studies extended to professionals involved with the European, US and Canadian regulatory systems.

The role delineation research indicated the unique knowledge base of the profession, which extends through the healthcare product lifecycle and blends content from the sciences, law and business. These studies also indicated consistency in the general scope of responsibilities of the professionals at this level, distinct from geographic location. However, these studies focused on only one level of the profession.

The RA profession today encompasses multiple levels, from the professional at entry level through the highly experienced professional with extensive technical knowledge and management responsibilities. RAPS' ongoing research on the scope of practice of RA professionals¹ indicates changes in their specific responsibilities and activities at different stages of their careers. However, these studies are not designed to collect detailed information about specific responsibilities or the knowledge and skills needed to successfully undertake these activities. Instead, RAPS considers this information vital to its role of supporting and advancing the RA profession and to providing the basis for relevant continuing education and professional development. Consequently, RAPS initiated a multi-year role delineation-type research effort to develop a framework for describing the scope of practice and responsibilities of the RA professional at different career stages and associated knowledge and skills. This initiative resulted in the Professional Development Framework (PD Framework).

The PD Framework provides a general model for describing the RA profession at the four career stages delineated in this project.² For each level, the framework presents tasks and responsibilities organized according to the stages and steps in the healthcare product lifecycle (**see Figure 1**), as well as the associated knowledge and skills required by the professional.

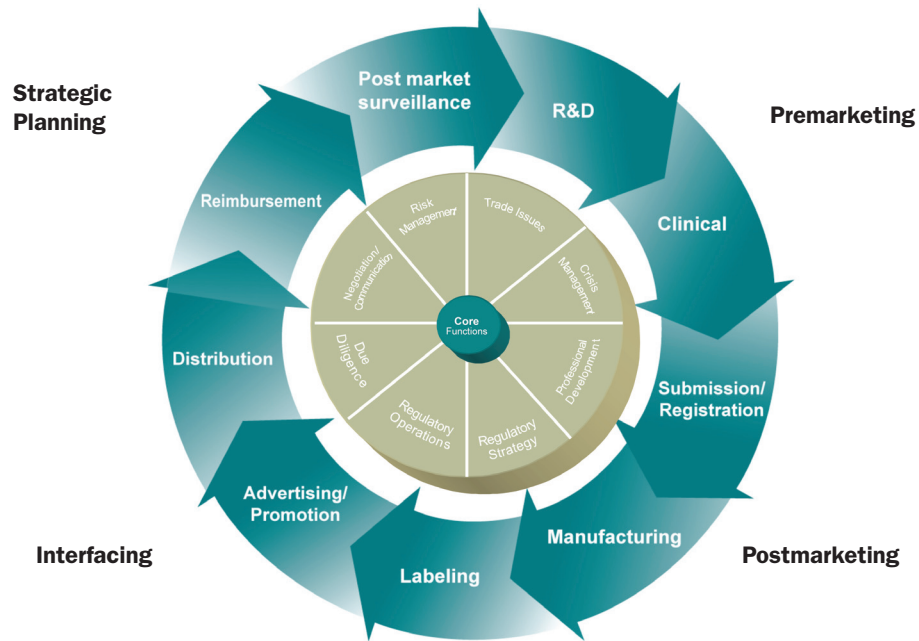
The research and development of the framework were undertaken to ensure it applies to professionals in industry, government, research and clinical settings, and is not product-specific. Further, the framework is not based upon specific regulatory systems or geography. The framework is not intended to provide all the details of the scope of practice or responsibilities of regulatory professionals. Nor is it intended to be a prescriptive description of the required knowledge, skills or competencies of the professional. However, the framework does provide a foundation from which we can describe the evolution of professionals in their careers and develop guides for professional development.

1 RAPS undertakes biennial studies on the general scope of practice and compensation of RA professionals in the US, Canada and European Union. These studies offer general trends in scope of practice by position/title, regulatory experience, employer and other factors but are not designed to collect more detailed information about specific roles and responsibilities.

2 Additional levels may be defined in future updates to this ongoing RAPS initiative.

Figure 1

RA Profession: Integral to the Healthcare Product Lifecycle



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APPROACH

The approach to developing the PD Framework was adapted from the detailed role delineation studies (job analyses) used to develop professional certification examinations, including the RAC. The early stages of this project were guided by a psychometrician with extensive experience in research and professional certification who also advised the RAC program.

From 2003 through 2007, RAPS members served as advisors on multiple special task forces created to undertake this initiative. The task forces consisted of senior regulatory professionals representing diversity in product responsibility, professional responsibility, company structure and geographic responsibility. The task forces developed comprehensive outlines of the scope of RA professional practice and associated knowledge and skills for professionals at designated career stages: new; midlevel (approximately five to 10 years of professional experience); and senior/executive level. The detailed outlines were validated through comprehensive surveys followed by a series of focus groups. More than 500 regulatory professionals were involved in the development and validation processes over a two-year period. The outlines for the professional with three to five years of experience (the RAC level) were adapted from data from the RA role delineation studies. Findings were analyzed and reviewed by the original task force and then by a newly appointed global task force that also reviewed the final model and accompanying materials.

PROFESSIONAL DEVELOPMENT FRAMEWORK

The PD Framework is based on two primary dimensions: **Level**, referring to one of four professional/career levels and **Domains**, which reflect scope of responsibilities throughout the product lifecycle. The levels and domains are organized within the framework by premarket and postmarket stages of product development, strategic planning and interfacing activities. For each level and domain, the PD Framework presents major **Basic Knowledge** (professional), **Skills/Abilities** (professional and interpersonal/business-related), and **Institutional Knowledge**.

PROFESSIONAL LEVELS

The PD Framework currently describes the RA profession at four stages. While the development of the framework did not attempt to assign job titles to specific levels, examples of relevant titles are included in the summaries below.

Level I

These individuals are new or relatively new to the profession with limited or no regulatory affairs knowledge. Many have education and/or experience in science, clinical studies or engineering and understand specific aspects of the healthcare product arena. Throughout Level I, these individuals develop basic knowledge and understanding of the regulatory and legal frameworks, regulatory requirements, legislation, processes and procedures.

Level I professionals should possess skills such as project management, writing, coordination, and interpersonal and communication skills. A science background and basic statistical knowledge are advantages. At this level, individuals coordinate and support technical and scientific regulatory activities. There is less focus on technical skills and more focus on project coordination and support. *(Example job titles: coordinator and some associate positions)*

Level II

Level II professionals develop and expand upon an integrated understanding of regulatory affairs as it applies throughout the product lifecycle. There is a strong emphasis on technical aspects of the profession, combined with scientific understanding and strong project management. Level II professionals often expand their involvement in international/multinational regulatory issues and begin more active involvement with concepts of regulatory strategy. They perform technical and scientific regulatory activities.

At Level II, individuals demonstrate knowledge and skills in areas such as, but not limited to, regulatory pathways and options; documentation; risk-benefit analysis; communication and collaboration internally and externally; working with vendors and subcontractors; submission, registration, obtaining approval, documentation, compliance, postmarketing surveillance/vigilance; and distribution. These individuals focus on hands-on training to strengthen and develop new skills and knowledge.

Regulatory Affairs Certification is targeted to professionals at this level. *(Example job titles: some associate positions, specialist, and some assistant manager and manager positions)*

Level III

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

Individuals at this level have strong technical and management skills and are actively engaged in regulatory strategy and operations. They are often engaged in activities spanning the product lifecycle and are involved in business/organizational activities, management and strategy. Level III professionals demonstrate skills and knowledge in areas such as, but not limited to: strategy development, risk assessment and management; monitoring and communicating change in the regulatory environment as well as global communication; staff and vendor development and management; and influencing the regulatory environment. *(Example job titles: manager, associate director, director)*

Level IV

Level IV professionals are strategic and “innovative.” They assume a strategic lead role representing the regulatory perspective while proactively developing new and often innovative approaches for pursuing business objectives within the regulatory framework. Some of the most important facets of the Level IV professional’s scope of practice are responsibilities and tasks related to strategic planning and interfacing throughout the product lifecycle, both within the organization and with diverse external groups.

Based upon a strong and extensive understanding of the role of the profession in the product lifecycle and the dynamics of regulatory processes, these professionals are also engaged in policy development within their organizations and with external groups. They typically are leaders and mentors within their organization and for the profession. At Level IV, professionals must be able to work effectively in multinational/multicultural environments. *(Example job titles: may include directors in some organizations, vice president, executive director, chief regulatory officer)*

DOMAINS

Domains represent the major content categories within each level of the PD Framework. The four domains are organized to encompass major tasks and responsibilities of the RA professional throughout the product lifecycle.

The PD Framework domains are:

- Strategic planning: encompassing regulatory strategy throughout the lifecycle; access to and organization of regulatory information and knowledge; integration of regulatory perspectives into the organization; and regulatory policies and procedures. At Levels III and IV, this domain also includes integration of regulatory strategy and policy into overall organizational approaches. Responsibilities described under this domain apply throughout the lifecycle.
- Premarketing: encompassing research and development; and preclinical and clinical phases through submission/registration.

- Postmarketing: encompassing reporting, compliance and postmarket surveillance; inspections; labeling; advertising and promotion; and sales-related responsibilities.
- Interfacing: responsibilities extending throughout the lifecycle, encompassing communication and interaction within the organization; with regulatory agencies, and professional trade and standards organizations; and with other stakeholders.

Responsibilities and tasks listed under each domain represent the major activities reported by RA professionals at each level. It is important to note that some responsibilities/tasks apply to multiple phases in the product lifecycle, even if they are listed under one domain. Further, the responsibilities and tasks described may not fully capture the activities of each RA professional. The nature of the organization, the education and previous experience of the professional and other factors may de-emphasize some responsibilities listed in the framework and/or add tasks and responsibilities.

The framework summarizes the knowledge, skills and abilities of the RA professional at each level by domain. Many facets of knowledge and skills apply to all professional levels. Generally, during early professional stages (Levels I and II), the RA professional builds a solid understanding of regulations, regulatory processes and procedures throughout the lifecycle. The applications of this knowledge and the skills at these levels are typically tactical. At Levels III and IV, RA professionals build on their knowledge and skill base, adding increasing strategic and management qualifications. Professionals at these levels are often less-focused on tactical elements of regulatory affairs and more engaged in broad-scale, strategic perspectives.

USE OF THE FRAMEWORK

The PD Framework is intended as a basic guide to the scope of practice and evolution of the RA professional. The framework provides an outline of the responsibilities, knowledge and skills of the professional at four stages of professional development. As such, the framework offers a tool for career/professional development planning by the individual professional, the regulatory manager and mentor, and by organizations.

The framework is not intended to be detailed or precisely tailored to the specific structure, product focus or nature of every organization. Thus, individuals and organizations should use it as a basic foundation, refining its content with additional details relevant to the individual and organization. The PD Framework is also an important tool for developing continuing education plans.

Additional tools and approaches for customizing and refining the PD Framework are available from RAPS.

RA PROFESSIONAL DEVELOPMENT FRAMEWORK - LEVEL I

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

	Tasks/Responsibilities	Basic Knowledge of	Skills or Ability to	Institutional Knowledge of
Knowledge, Skills and Abilities Throughout the Product Lifecycle		<ul style="list-style-type: none"> Ethics and product lifecycle Standard operating procedures (SOPs) Product history, profile, specifications, standards, safety issues, reimbursement, precedents and approval Regulatory history, guidelines, policies, standards, practices, requirements and precedents Regulatory agency structure, processes and key personnel Principles and requirements of food and drug laws International treaties and regional, national, local and territorial trade requirements, agreements and considerations 	<ul style="list-style-type: none"> Apply business and RA ethical standards Think analytically and critically Communicate effectively verbally and in writing Work with cross-functional teams Review and analyze documentation Write and edit technical documents Meet deadlines Handle detailed tasks and prioritize them Manage projects 	<ul style="list-style-type: none"> Company SOPs Department SOPs Company history, philosophy, culture, policies, processes, goals, code of ethics and position
Strategic Planning	<ul style="list-style-type: none"> Assist in SOP development and review Stay abreast of regulatory procedures and changes in regulatory climate Maintain records on legislation, regulations and guidelines Investigate regulatory history of similar products to assess approval implications Conduct research on submission requirements and options Assist in monitoring and reporting project timelines Respond to RA information requests Monitor and utilize tracking and control systems 	<ul style="list-style-type: none"> Medical terminology Regulatory terminology Domestic regulatory markets International regulatory markets Submission types and requirements 	<ul style="list-style-type: none"> Research and locate information on regulatory requirements and similar products 	<ul style="list-style-type: none"> Key company contacts
Premarketing	<ul style="list-style-type: none"> Organize materials from preclinical and clinical studies for review and assist in review process Compile and organize materials for presubmission reports Coordinate and assist in the preparation of submission packages for regulatory agencies Implement submission templates Oversee quality control of regulatory documents and submissions Monitor applications under regulatory review Maintain regulatory files Organize meetings with regulatory agency staff 	<ul style="list-style-type: none"> GxPs (GCPs, GLPs, GMPs) Electronic submission techniques, types and requirements Clinical research, clinical operations, nonclinical and quality requirements 		<ul style="list-style-type: none"> Company information management systems

	Tasks/Responsibilities	Basic Knowledge of	Skills or Ability to	Institutional Knowledge of
Postmarketing	<ul style="list-style-type: none"> Update and maintain paper/electronic document archival systems Assist in the preparation of routine reports and regulatory agency communications Assist in the review of public communication for regulatory perspectives Assist in the review of advertising and promotional items Coordinate internal audits and inspections Assist in the preparation of postmarket reports and submissions Track product events, complaints and recalls 	<ul style="list-style-type: none"> GxPs (GCPs, GLPs, GMPs) Approval status in other markets Principles and requirements of promotion, advertising and labeling Submission types and requirements Import/export requirements 		<ul style="list-style-type: none"> Company information management systems
Interfacing	<ul style="list-style-type: none"> Provide information on regulatory requirements to other departments and/or business units Participate in product and/or regulatory teams to coordinate documentation Maintain records to comply with regulatory requirements Compose routine correspondence to regulatory agencies Interact with outside experts, partners and regulatory agencies, as requested Assist in preparing for technical meetings with regulatory agencies 	<ul style="list-style-type: none"> Principles and requirements of promotion, advertising and labeling Submission types and requirements 	<ul style="list-style-type: none"> Analyze relevant data and information 	<ul style="list-style-type: none"> Key company contacts Internal inspection procedures Communication routes

RA PROFESSIONAL DEVELOPMENT FRAMEWORK - LEVEL II

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

	Tasks/Responsibilities	Basic Knowledge of	Skills or Ability to	Institutional Knowledge of
Knowledge, Skills and Abilities Throughout the Product Lifecycle	<ul style="list-style-type: none"> Track and keep records Manage internal review processes Communicate with scientific and regulatory personnel 	<ul style="list-style-type: none"> International treaties and regional, national, local and territorial trade requirements, agreements and considerations Domestic and international regulatory guidelines, policies and regulations Product profiles, specifications, standards and history Regulatory history, guidelines, policies, standards, practices, requirements and precedents specific to the product Standard operating procedures (SOPs) Regulatory agency structure, processes and key personnel Ethical guidelines of the RA profession, clinical research and regulatory process 	<ul style="list-style-type: none"> Apply business and RA ethical standards Communicate with diverse audiences and personnel Work with cross-functional teams Write and edit technical documents Think analytically Manage projects Create project plans and timelines Organize and track complex information Negotiate internally and externally with regulatory agencies 	<ul style="list-style-type: none"> Company history, philosophy, culture, policies, processes, goals, code of ethics and position Department SOPs Company SOPs
Strategic Planning	<ul style="list-style-type: none"> Assist in SOP development and review Assist in the development of regulatory strategy and update strategy based upon regulatory changes Provide regulatory input to product lifecycle planning Evaluate regulatory impact on proposed products Understand, investigate and evaluate regulatory history/background of class, disease/therapeutic/diagnostic context in order to assess regulatory implications for approval Determine trade issues to anticipate regulatory obstacles Determine and communicate submission and approval requirements Participate in risk-benefit analysis for regulatory compliance Continue to revisit and compare regulatory outcomes with initial product concepts to make recommendations on future actions 	<ul style="list-style-type: none"> Research methods External regulatory environment affecting the industry Fundamental processes, standards and practices for regulatory approval Differences in legislative authorities Needs/impact analysis Lifecycle planning and management 	<ul style="list-style-type: none"> Communicate and network with scientific and regulatory personnel to obtain relevant information Translate and communicate technical regulatory issues for nontechnical audiences Research, analyze, integrate and organize background information from diverse sources Assess and interpret regulatory requirements and their impact Communicate clear and balanced evaluations Perform due diligence Apply risk-benefit analysis techniques Assess product's market viability 	<ul style="list-style-type: none"> Key company contacts Present and future competitive landscape of similar products

	Tasks/Responsibilities	Basic Knowledge of	Skills or Ability to	Institutional Knowledge of
Premarketing	<ul style="list-style-type: none"> • Advise responsible personnel on regulatory requirements for quality, preclinical and clinical data requirements for clinical study applications or marketing applications • Evaluate proposed preclinical, clinical and manufacturing changes for regulatory filing strategies • Assess the acceptability of quality, preclinical and clinical documentation for submission filing to comply with regulatory requirements for clinical trials, marketing applications and corporate goals, to secure submission approval • Coordinate and execute preapproval compliance activities • Monitor impact of changing regulations on submission strategies • Identify issues early in the submission preparation process that could impact product launch • Compile, prepare, review and submit regulatory submission to authorities • Monitor and submit applicable reports and ensure appropriate responses are submitted to regulatory authorities • Negotiate and interact with regulatory authorities during the development and review process to ensure submission approval 	<ul style="list-style-type: none"> • Submission types and requirements • Electronic submission requirements • Clinical research, clinical operations and nonclinical and quality regulatory requirements • Appeals processes • GxPs (GCPs, GLPs, GMPs) 	<ul style="list-style-type: none"> • Communicate with internal stakeholders and regulatory authorities • Write, review and prepare complex documents • Prepare applications and regulatory documentation • Review acceptability of quality, preclinical and clinical documentation and data, statistical methods and analysis • Review and assess regulatory submissions • Utilize electronic submission techniques • Assess the regulatory impact on filing strategies • Apply risk-benefit analysis techniques 	<ul style="list-style-type: none"> • Key company contacts

	Tasks/Responsibilities	Basic Knowledge of	Skills or Ability to	Institutional Knowledge of
Postmarketing	<ul style="list-style-type: none"> • Maintain annual licenses, registrations, listings and patent information • Review regulatory aspects of contracts • Ensure compliance with product postmarketing approval requirements • Approve advertising and promotional items for compliance before release • Generate and approve labeling for compliance before release • Review publicly disseminated information to minimize regulatory exposure, review product claims and preserve confidentiality of applicable product information • Provide regulatory input for and appropriate follow-up to inspections and audits • Assist in the development and implementation of SOPs and systems to track and manage product-associated events • Submit and review change controls to determine the level of change and consequent submission requirements • Contribute to the development and functioning of the crisis/issue management program • Participate in ensuring adequacy of product traceability systems • Identify product-associated problems and develop proposals for solutions • Ensure product safety issues and product-associated events are reported to regulatory agencies • Provide regulatory input for product recalls and recall communications 	<ul style="list-style-type: none"> • GxP (especially GMP) quality systems • Advertising and promotional approaches and related regulatory perspectives • Risk management • Manufacturing processes • Quality systems • Product labeling issues • Product registration and patent requirements 	<ul style="list-style-type: none"> • Work in diversified team environments to leverage a broad viewpoint on problem resolution • Plan training and education for a variety of stakeholders • Manage access to information requests • Write competitive statements that are clear, accurate and supported by the data • Interpret regulations, advertising messages and data to ensure consistency with approved labeling • Review marketing and promotional materials • Edit public messages to ensure compliance with regulatory practice • Write and review product labels • Write and review reports and follow-up communication with regulatory agencies • Develop objective analyses for management • Evaluate options and recommend viable solutions to management • Communicate deficiencies to discipline experts (e.g., medical, legal, corporate) • Write internal correspondence that describes SOP gaps or deficiencies • Edit contract texts to accurately convey information pertaining to delegated regulatory activities • Apply crisis assessment techniques 	<ul style="list-style-type: none"> • Company information management systems
Interfacing	<ul style="list-style-type: none"> • Provide training for staff on current and new regulatory requirements • Communicate regulatory agency/industry positions within the regulatory department • Problem-solve with and advise internal stakeholders on regulatory issues • Communicate and negotiate with regulatory authorities and stakeholders • Conduct and participate in technical meetings with regulatory advisory committees and agencies • Accompany inspection team(s) as required • Notify, consult or brief legal counsel when appropriate • Identify standards for the organization's products • Participate in professional associations, industry/trade groups (local/regional/international) and appropriate standards organizations 	<ul style="list-style-type: none"> • Principles of team dynamics • Inspection authority and requirements • Role of professional, trade and standards organizations • Standards development 	<ul style="list-style-type: none"> • Network with internal/external colleagues • Build teams • Negotiate industry and regulatory positions • Organize meetings • Develop and deliver technical presentations • Communicate proposed regulations to internal stakeholders • Communicate regulatory requirements to scientific/medical/technical experts • Analyze regulatory requirements and their implications • Identify regulatory problems • Apply risk-benefit analysis techniques • Interpret regulatory impact on the company 	<ul style="list-style-type: none"> • Internal inspection procedures • Internal routes of communication

RA PROFESSIONAL DEVELOPMENT FRAMEWORK - LEVEL III

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

Knowledge, Skills and Abilities Throughout the Product Lifecycle	Tasks/Responsibilities	Basic Knowledge of	Skills or Ability to	Institutional Knowledge of
		<ul style="list-style-type: none"> International treaties and regional, national, local and territorial trade requirements, agreements and considerations 	<ul style="list-style-type: none"> Apply ethical standards Perform risk assessment Plan and conduct meetings Manage projects 	<ul style="list-style-type: none"> Company history, philosophy, culture, policies, processes, goals, code of ethics and position
Strategic Planning	Tasks/Responsibilities	Basic Knowledge of	Skills or Ability to	Institutional Knowledge of
	<ul style="list-style-type: none"> Evaluate regulatory risks of corporate policies Recruit, manage, develop and mentor regulatory professionals Develop new regulatory policies, procedures and SOPs and train key personnel on them Assist in the development and advancement of policy and procedures for regulatory affairs and compliance to establish a compliant culture within the organization Utilize technical regulatory skills to propose strategies on complex issues Monitor emerging issues and identify solutions Monitor trade association positions for impact on company products Provide regulatory input to product lifecycle planning Anticipate regulatory obstacles and emerging issues throughout the product lifecycle and develop solutions with other members of regulatory and related teams Evaluate the effect of regulatory requirements on product positions Assist in the development of global, regional and multicountry regulatory strategy and update strategy based upon regulatory changes Determine submission and approval requirements Monitor regulatory outcomes of initial product concepts and provide input to senior regulatory management Assist in regulatory due diligence 	<ul style="list-style-type: none"> Domestic regulatory markets International regulatory markets Due diligence process Regulatory intelligence, acquisitions and partnerships and internal or external license opportunities External regulatory environment affecting the industry 	<ul style="list-style-type: none"> Assess regulatory impact and risk Compile and synthesize relevant data to complete regulatory submissions 	<ul style="list-style-type: none"> Key company contacts Department SOPs Company SOPs

	Tasks/Responsibilities	Basic Knowledge of	Skills or Ability to	Institutional Knowledge of
Premarketing	<ul style="list-style-type: none"> • Provide strategic input and technical guidance on regulatory requirements to development teams • Evaluate risk of and regulatory solutions to product and clinical safety issues during clinical phases and recommend solutions • Evaluate proposed preclinical, clinical and manufacturing changes for regulatory filing strategies • Manage and execute preapproval compliance activities • Assess the acceptability of quality, preclinical and clinical documentation for submission filing • Negotiate and interact with regulatory authorities during the development and review process to ensure submission approval • Identify issues early in the submission preparation process that could impact product launch • Monitor impact of changing regulations on submission strategies and update internal stakeholders • Prepare regulatory submissions • Monitor and submit applicable reports and responses to regulatory authorities • Monitor applications under regulatory review • Propose risk-based decisions on special access approval with appropriate regulatory agencies to pursue approvals based on patient needs and risk assessment 	<ul style="list-style-type: none"> • Specific requirements for preclinical data relevant to the product • Clinical trial design • Statistics • Quality standards specific to the product • GxPs (GCPs, GLPs, GMPs) • Therapeutic regulatory precedents and applications of products • Submission requirement processes • Electronic submission process • Risk-benefit assessment methodology • Regulatory agency inspection and compliance policies • Appeals processes • Prior agreements with regulatory agencies on product or related products, regulatory precedents, prospects • Limitations of regulatory authority • Global safety reporting requirements • Present and future competitive landscape of similar products 	<ul style="list-style-type: none"> • Determine product regulatory path or class • Define data to support product claims • Interpret and evaluate data • Review regulatory submissions • Approve regulatory filing strategies based upon proposed preclinical, clinical and manufacturing changes • Assess regulatory impact and risk • Develop regulatory and registration plans with specific deliverables and timelines • Integrate business and clinical objectives with regulatory requirements • Advise stakeholders of regulatory options and status • Work with regulators and provide feedback to them • Implement processes to ensure compliance 	<ul style="list-style-type: none"> • Company business objectives and claims of product and marketing environment

Postmarketing	Tasks/Responsibilities	Basic Knowledge of	Skills or Ability to	Institutional Knowledge of
	<ul style="list-style-type: none"> • Maintain annual licenses, registrations, listings and patent information • Ensure compliance with product postmarketing approval requirements • Review and approve labeling to ensure compliance with regulations and company policy • Review and approve advertising and promotional items to ensure regulatory compliance • Assess external communications relative to regulations • Review publicly disseminated information to minimize regulatory exposure, review product claims and preserve confidentiality of applicable product information • Review and approve required reports, supplemental submissions and other postmarketing commitments to update and maintain product approvals and registrations • Provide regulatory input for and appropriate follow-up to inspections and audits • Develop, implement and manage appropriate SOPs and systems to track and manage product-associated events • Submit/review change controls to determine the level of change and consequent submission requirements • Actively contribute to the development and functioning of the crisis/issue management program • Identify product-associated problems and develop proposals for solutions • Provide regulatory input for product recalls and recall communications • Manage system to ensure that product safety issues and product-associated events are reported to regulatory agencies • Report adverse events to regulatory agencies and internal stakeholders 		<ul style="list-style-type: none"> • Generate timely, complete and accurate updates • Select and use appropriate information systems • Interpret regulatory requirements and guidelines • Identify confidential and proprietary information • Apply risk-assessment techniques • Assess need for postmarketing submissions • Review and approve inspection and audit communications • Recommend corrective actions to management • Negotiate with regulatory agencies • Address safety issues while maintaining commercial viability of product • Strategize processes for marketing products and crafting product claims • Manage access to information requests • Evaluate options and recommend viable solutions to management 	<ul style="list-style-type: none"> • Company history, philosophy, culture, policies, processes, goals, code of ethics and position • Company information management systems

Interfacing	Tasks/Responsibilities	Basic Knowledge of	Skills or Ability to	Institutional Knowledge of
	<ul style="list-style-type: none"> • Provide training for stakeholders on current and new regulatory requirements to ensure company-wide compliance • Communicate regulatory agency/industry positions to internal stakeholders • Strategize with and advise internal stakeholders on regulatory issues • Communicate and negotiate with regulatory authorities and stakeholders • Conduct technical meetings with regulatory advisory committees and government agencies • Communicate the impact of new, existing and pending regulations, guidelines and standards, and review committee recommendations to regulatory staff and internal stakeholders • Participate in medical/scientific review and other relevant committees • Accompany inspection team(s) as required • Notify, consult or brief legal counsel when appropriate • Participate and take leadership role in professional associations, industry/trade groups (local/regional/international) and appropriate standards organizations 	<ul style="list-style-type: none"> • Regulatory agency and stakeholder decision makers of the regulatory agency and stakeholders • Structure of the regulatory agency(s) • Principles of regulatory compliance • External communication routes • Due diligence process • Product profiles • Risk-benefit assessment methodology • Legal framework and potential actions • Differences in legislative authorities • Process to develop new legislation and regulation • Developing, pending and recent legislation, regulations and guidelines • Inspection authority and process • Standards organizations and standards development process • Reimbursement process and requirements • Current scientific trends • Competitive environment • Current issues facing industry 	<ul style="list-style-type: none"> • Work effectively across different cultures and languages • Communicate with scientific, technical, business and public organizations • Present complex information • Translate regulatory language into meaningful business terms • Synthesize applicable data requirements • Analyze regulatory requirements and their implications • Assess compliance in technical presentations • Apply risk-benefit analysis techniques • Identify regulatory and legal impact on organization • Manage inspections and audits 	<ul style="list-style-type: none"> • Key company contacts • Internal communication routes • Internal inspection procedures • Training requirements

RA PROFESSIONAL DEVELOPMENT FRAMEWORK - LEVEL IV

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

Knowledge, Skills and Abilities Throughout the Product Lifecycle	Tasks/Responsibilities	Basic Knowledge of	Skills or Ability to	Institutional Knowledge of
	<ul style="list-style-type: none"> Assign and manage functional groups in the development of relevant data to complete a regulatory submission 	<ul style="list-style-type: none"> Product profile, specifications, standards and history Regulatory history, guidelines, policies, standards, practices, requirements and precedents specific to the product Regulatory agency structure, processes and key personnel International treaties and regional, national, local and territorial trade requirements, agreements and considerations 	<ul style="list-style-type: none"> Apply business and RA ethical standards Plan and conduct meetings Manage projects and teams 	<ul style="list-style-type: none"> Company history, philosophy, culture, policies, processes, goals, code of ethics and position
Strategic Planning	Tasks/Responsibilities	Basic Knowledge of	Skills or Ability to	Institutional Knowledge of
	<ul style="list-style-type: none"> Participate in developing/ updating organizational code of ethics Recruit, develop, manage and mentor regulatory professionals to contribute to organizational/ human capital planning Provide strategic guidance for resource and development planning Assess emerging issues and develop solutions to them Develop solutions to address issues with other members of management and stakeholders Develop corporate positions on regulatory risk-benefit Identify need for new regulatory policies, procedures and SOPs and approve them Develop and advance the organization's policy and procedures for regulatory affairs and compliance to establish a compliant culture Develop strategies for complex issues with potential for significant regulatory compliance impact Anticipate regulatory and related obstacles and emerging issues throughout the product lifecycle Provide strategic guidance for product development and planning throughout the product lifecycle Create and develop product positioning strategies based upon regulatory requirements Integrate regulatory considerations into the corporation's global product entry and exit strategy Analyze and compare regulatory outcomes with initial product concepts and recommend future strategies and actions Develop global, regional and multicountry regulatory strategies and update based upon regulatory changes 	<ul style="list-style-type: none"> Key company contacts Routes of communication Research and development methods Needs/impact analysis Due diligence process Differences in legislative authorities Fundamental processes, standards and practices for regulatory approval Regulatory requirements applied throughout the lifecycle to meet regulatory and reimbursement requirements and business objectives Domestic and international regulatory guidelines, policies and regulations External regulatory environment affecting the industry Strategic planning, business processes, project management 	<ul style="list-style-type: none"> Think analytically Understand good management practices Collaborate across functional groups Establish and maintain relationships with regulatory personnel Communicate effectively with diverse audiences Translate technical regulatory issues into understandable language Integrate information from diverse sources Develop SOPs Apply risk-benefit analysis techniques Perform due diligence Anticipate issues or obstacles imposed by regulatory requirements Analyze regulatory guidelines, policies and actions to determine regulatory and legal impact on the company Assess regulatory impact and risk, and make risk management recommendations Create and manage strategic and project plans Assess market viability of products Develop multinational/global strategies 	<ul style="list-style-type: none"> Present and future competitive landscape of similar products Key company contacts

	Tasks/Responsibilities	Basic Knowledge of	Skills or Ability to	Institutional Knowledge of
Premarketing	<ul style="list-style-type: none"> • Provide strategic input on regulatory requirements to development teams • Evaluate risk and safety issues and recommend regulatory solutions during clinical phases • Manage preapproval compliance activities • Negotiate with regulatory authorities during the development and review process to ensure submission approval • Formulate company procedures to respond to regulatory authority queries • Identify and address issues early in the submission that could impact the product launch preparation process • Communicate application progress to internal stakeholders • Approve regulatory filing strategies based upon proposed preclinical, clinical and manufacturing changes • Make risk-based decisions on special access approvals based upon patient needs and risk assessment 	<ul style="list-style-type: none"> • All of the above • Regulatory agency inspection and compliance policies • Risk-benefit assessment methodology • Present and future competitive landscape of similar products • Company business objectives, product claims and marketing environment • Submission requirement processes • Electronic submission process • Therapeutic regulatory precedents and applications of products • Quality standards specific to the product • Specific requirements for preclinical data relevant to the product • Clinical trial design • Statistics • GxPs (GCPs, GLPs, GMPs) • Prior agreements with regulatory agencies on the product or related products; regulatory precedents and prospects • Appeals processes • Limitations of regulatory authority • Global safety reporting requirements 	<ul style="list-style-type: none"> • Advise stakeholders of regulatory options and recommend solutions • Strategize processes for marketing products and crafting product claims • Assess regulatory impact and risk • Select and implement systems to ensure compliance • Review regulatory submissions • Define data to support product claims • Create and implement crisis management plans and procedures • Develop optimal submission strategy and plans • Edit submissions to regulatory agencies • Articulate strategy rationale • Strategize processes for marketing products and crafting product claims in collaboration with internal stakeholders • Integrate business and clinical objectives with regulatory requirements • Formulate creative solutions that address issues and meet requirements and clinical and business goals • Monitor product development in other jurisdictions • Lead team in articulating science-based rationale to support company's response • Communicate complex technical information to nontechnical audiences verbally and in writing 	<ul style="list-style-type: none"> • Present and future competitive landscape of similar products

	Tasks/Responsibilities	Basic Knowledge of	Skills or Ability to	Institutional Knowledge of
Postmarketing	<ul style="list-style-type: none"> • Manage processes and personnel involved with maintaining annual licenses, registrations, listings and patent information • Ensure compliance with product postmarketing requirements • Review and approve required reports and supplemental submissions • Review and approve advertising and promotional items for regulatory compliance • Review and approve labeling to ensure compliance • Review and approve publicly disseminated information to minimize regulatory exposure; review product claims, and preserve confidentiality of applicable product information • Oversee regulatory aspects of business relationships to ensure compliance and protect corporate interests • Ensure a system is in place to manage access to information requests • Develop, implement and manage SOPs and systems to track and manage product-associated events • Review change controls for level of change and consequent regulatory notification • Provide regulatory input for follow-up to inspections and audits to minimize potential for findings of noncompliance • Lead crisis management program development and implementation • Identify and present option for risk mitigation to decision-makers • Develop a system to ensure product safety issues and product-associated events are reported to regulatory agencies • Report adverse events (AEs) • Represent regulatory affairs in product recall and recall communication process 	<ul style="list-style-type: none"> • Crisis management techniques • AER requirements and processes • Domestic and international regulatory markets • Limitations and strengths of various types of market interventions • GxPs (GCPs, GLPs, GMPs) • Business strategy • Risk management techniques • Information technology as applied to product distribution • Various market intervention limitations and strengths • Patterns of potential off-label product uses • Patterns of product misuse and abuse • Reimbursement approval requirements • Information, knowledge management and tracking systems • Product distribution issues 	<ul style="list-style-type: none"> • Assess nature and degree of product status change relative to listed regulatory criteria to compile corresponding submission • Assess need for postmarketing submissions • Select and use appropriate information systems • Generate timely, complete and accurate updates • Identify confidential and proprietary information • Interpret regulatory requirements and guidelines • Assess scenarios and recommend options and solutions • Address safety issues while maintaining commercial viability of products • Manage projects and teams • Manage inspections and audits • Review and approve inspection and audit communications • Perform risk assessment • Respond to risks to address safety issues while maintaining commercial viability of products • Negotiate with regulatory agencies • Review and approve external communications relative to regulations • Strategize processes for marketing products and crafting product claims 	<ul style="list-style-type: none"> • Company information management systems

	Tasks/Responsibilities	Basic Knowledge of	Skills or Ability to	Institutional Knowledge of
Interfacing	<ul style="list-style-type: none"> • Provide training for stakeholders on current and new regulatory requirements to ensure company-wide compliance • Develop, review and approve corporate-wide communications to ensure compliance and to meet business objectives • Advise management and stakeholders on complex regulatory issues requiring innovative solutions • Advise management of the impact of current, newly finalized or proposed regulations, guidelines and standards, and on review committee recommendations • Advise internal personnel on requirements and options for submissions and approvals • Influence clinical strategy to ensure integration into the regulatory and reimbursement position • Communicate the company's regulatory position to business partners • Manage communication and negotiation with regulatory authorities • Strategically plan and lead meetings with regulatory advisory committees and agencies • Utilize expert technical regulatory skills to influence regulators on complex issues • Conduct and present regulatory due diligence • Lead inspection team • Consult with and advise legal counsel on regulatory and legal issues • Participate in the development of new regulations, guidelines and/or standards to promote scientific innovation balanced with appropriate safety concerns • Advance the organization's position by participating and taking leadership roles in professional associations, industry and trade groups and appropriate standards organizations 	<ul style="list-style-type: none"> • Regulatory agency and stakeholder decision makers • Structure of the regulatory agency(s) • Principles of regulatory compliance • Routes of external communications • Differences in legislative authorities • Risk-benefit assessment methodology • Product profiles • Developing, pending and recent legislation, regulations and guidelines • Process to develop new legislation and regulation • Standards organizations and standards development process • Inspection authority and process • Due diligence process • Reimbursement process and requirements • Competitive environment • Current scientific trends • Current issues facing industry • Legal framework and potential actions 	<ul style="list-style-type: none"> • Effectively communicate with scientific, technical, business and public organizations • Analyze regulatory requirements and their implications • Assess compliance in technical presentations • Apply risk-benefit analysis techniques • Determine company regulatory and legal impact • Present complex information • Synthesize applicable data requirements • Translate regulatory language into practical business terms • Work effectively across different cultures and languages 	<ul style="list-style-type: none"> • Internal inspection procedures • Internal communication routes • Training requirements

ABOUT RAPS

The Regulatory Affairs Professionals Society (RAPS) guides and supports individuals—from industry, government, academia, research and clinical organizations—to bring life-saving and life-enhancing products to the global marketplace quickly and safely.

Founded in 1976 and operating outside the political arena, RAPS provides a neutral forum on emerging science and global regulatory challenges, offering personal and professional resources to help RA professionals continuously improve and work smarter, faster and in compliance with regulatory models.

RAPS established the regulatory profession worldwide and brings knowledge and progress to it. By identifying scope of practice, defining core competencies, upholding professional standards, developing professional certification, and providing educational and networking opportunities, RAPS supports professionals throughout the healthcare product lifecycle.

For more information, visit www.raps.org.



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