RAPS
Regulatory Competency Framework

RAPS
REGULATORY AFFAIRS
PROFESSIONALS SOCIETY
Driving Regulatory Excellence™

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RAPS Overview

- Established in 1976
- Non-political, independently funded, not-for-profit
- Headquartered in metro Washington, DC
- Chapters and affiliates throughout North America, Asia, Europe and Latin America

RAPS Members

- 15,000 individual members in 80 countries
- Members from industry, government, research, academic and clinical organizations

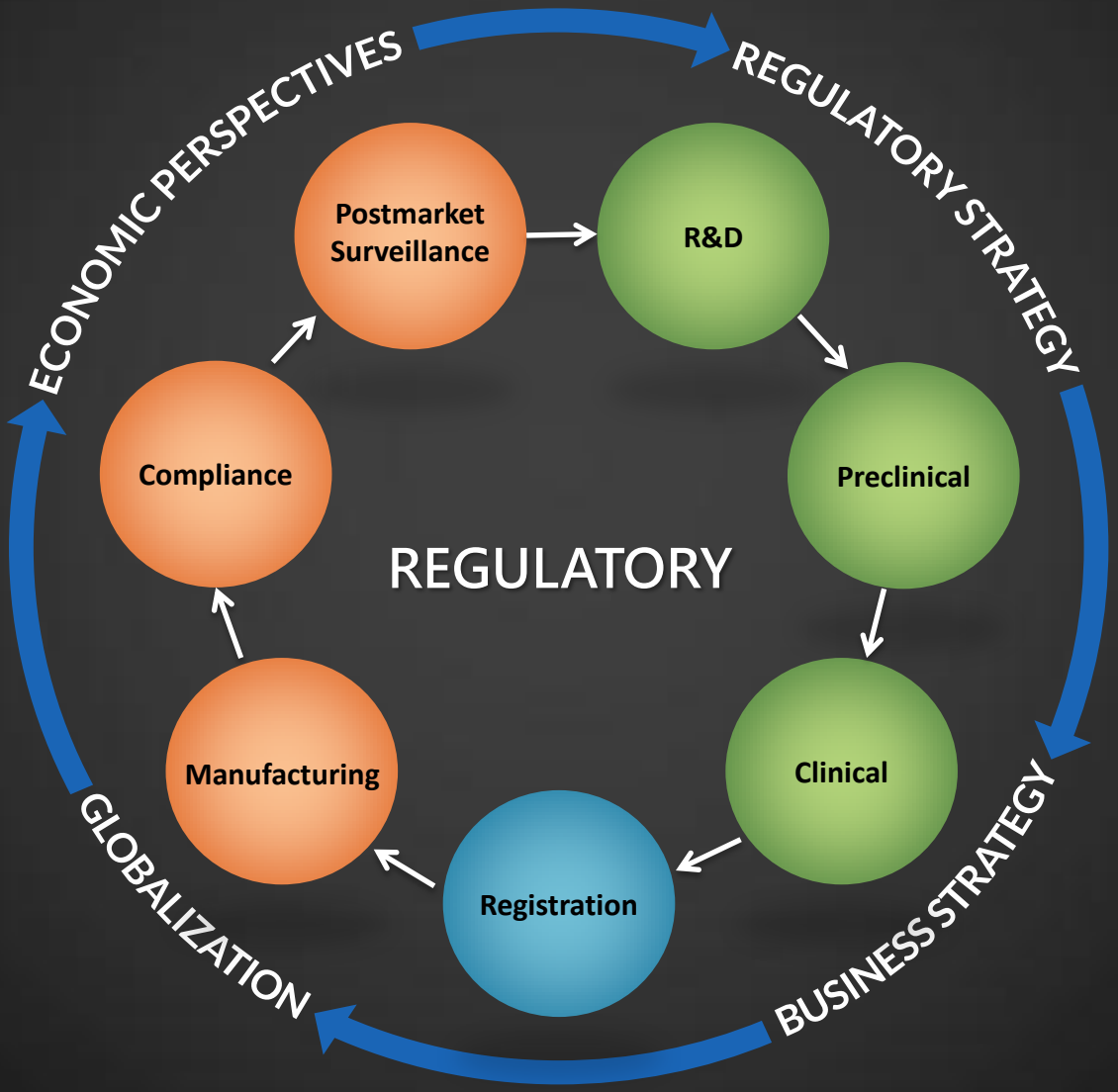
RAPS Initiatives

- Studies the changing role of the regulatory profession
- Facilitates careful study and balanced discussion of changes shaping the regulation of healthcare products worldwide
- Develops standards for knowledge, competency, ethics

RAPS Mission

- Develop and sustain a competent global regulatory workforce that drives good regulatory practice and policy to advance public health.

Healthcare Product Lifecycle



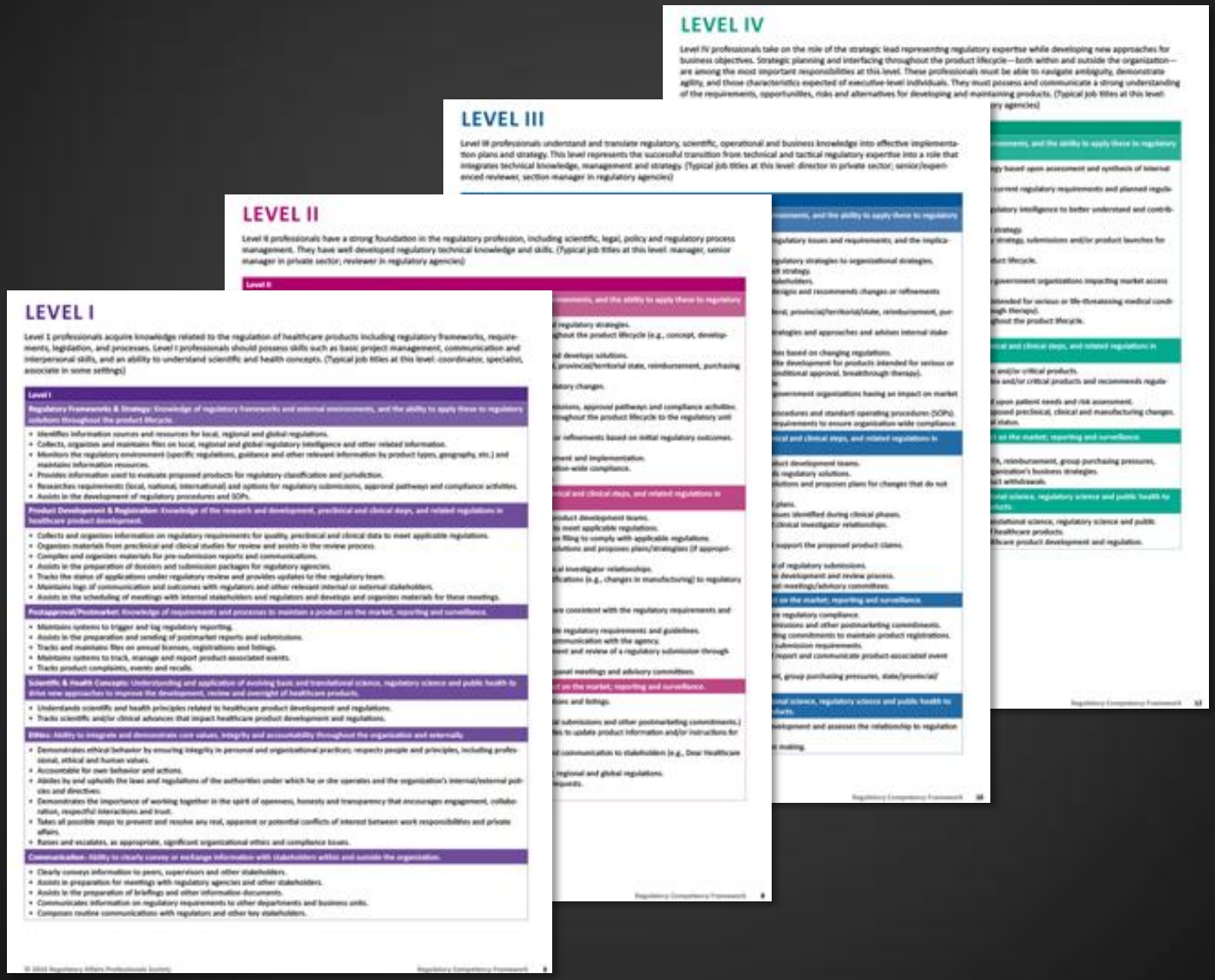
RAPS Regulatory Competency Framework

Professional Levels

LEVEL 4	Executive regulatory leader and strategist *Typical job titles (industry): VP, executive director, CEO; (regulators): division director, agency director*
LEVEL 3	Translate regulatory, scientific, operational and business knowledge into strategy *Typical job titles (industry): director; (regulators): senior reviewer, section manager*
LEVEL 2	Regulatory technical expertise; managing regulatory functions *Typical job titles (industry): manager, senior manager; (regulators): reviewer*
LEVEL 1	Support work of regulatory team; building regulatory knowledge base *Typical job titles (industry): coordinator, specialist*

Professional Competency Domains

Competencies for Each Career Level



LEVEL IV

Level IV professionals take on the role of the strategic lead representing regulatory expertise while developing new approaches for business objectives. Strategic planning and interfacing throughout the product lifecycle—both within and outside the organization—are among the most important responsibilities at this level. These professionals must be able to navigate ambiguity, demonstrate agility, and those characteristics expected of executive-level individuals. They must possess and communicate a strong understanding of the requirements, opportunities, risks and alternatives for developing and maintaining products. (Typical job titles at this level:

LEVEL III

Level III professionals understand and translate regulatory, scientific, operational and business knowledge into effective implementation plans and strategy. This level represents the successful transition from technical and tactical regulatory expertise into a role that integrates technical knowledge, management and strategy. (Typical job titles at this level: director in private sector; senior/experienced reviewer, section manager in regulatory agencies)

LEVEL II

Level II professionals have a strong foundation in the regulatory profession, including scientific, legal, policy and regulatory process management. They have well developed regulatory technical knowledge and skills. (Typical job titles at this level: manager, senior manager in private sector; reviewer in regulatory agencies)

LEVEL I

Level I professionals acquire knowledge related to the regulation of healthcare products including regulatory frameworks, requirements, legislation, and processes. Level I professionals should possess skills such as basic project management, communication and interpersonal skills, and an ability to understand scientific and health concepts. (Typical job titles at this level: coordinator, specialist, associate in some settings)

Level I

Regulatory Frameworks & Strategy: Knowledge of regulatory frameworks and external environments, and the ability to apply these to regulatory solutions throughout the product lifecycle.

- Identifies information sources and resources for local, regional and global regulations.
- Collects, organizes and maintains files on local, regional and global regulatory intelligence and other related information.
- Monitors the regulatory environment (specific regulations, guidance and other relevant information by product types, geography, etc.) and maintains information resources.
- Provides information used to evaluate proposed products for regulatory classification and jurisdiction.
- Researches requirements (local, national, international) and options for regulatory submissions, approval pathways and compliance activities.
- Assists in the development of regulatory procedures and SOPs.

Product Development & Registration: Knowledge of the research and development, preclinical and clinical steps, and related regulations in healthcare product development.

- Collects and organizes information on regulatory requirements for quality, preclinical and clinical data to meet applicable regulations.
- Organizes materials from preclinical and clinical studies for review and assists in the review process.
- Compiles and organizes materials for pre-submission reports and communications.
- Assists in the preparation of dossiers and submission packages for regulatory agencies.
- Tracks the status of applications under regulatory review and provides updates to the regulatory team.
- Maintains logs of communication and outcomes with regulators and other relevant internal or external stakeholders.
- Assists in the scheduling of meetings with internal stakeholders and regulators and develops and organizes materials for these meetings.

Postapproval/Postmarket: Knowledge of requirements and processes to maintain a product on the market, reporting and surveillance.

- Maintains systems to trigger and log regulatory reporting.
- Assists in the preparation and sending of postmarket reports and submissions.
- Tracks and maintains files on annual licenses, registrations and listings.
- Maintains systems to track, manage and report product-associated events.
- Tracks product complaints, events and recalls.

Scientific & Health Concepts: Understanding and application of evolving basic and translational science, regulatory science and public health to drive new approaches to improve the development, review and oversight of healthcare products.

- Understands scientific and health principles related to healthcare product development and regulations.
- Tracks scientific and/or clinical advances that impact healthcare product development and regulations.

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

- Demonstrates ethical behavior by ensuring integrity in personal and organizational practices; respects people and principles, including professional, ethical and human values.
- Accountable for own behavior and actions.
- Abides by and upholds the laws and regulations of the authorities under which he or she operates and the organization's internal/external policies and directives.
- Demonstrates the importance of working together in the spirit of openness, honesty and transparency that encourages engagement, collaboration, respectful interactions and trust.
- Takes all possible steps to prevent and resolve any real, apparent or potential conflicts of interest between work responsibilities and private affairs.
- Raises and escalates, as appropriate, significant organizational ethics and compliance issues.

Communication: Ability to clearly convey or exchange information with stakeholders within and outside the organization.

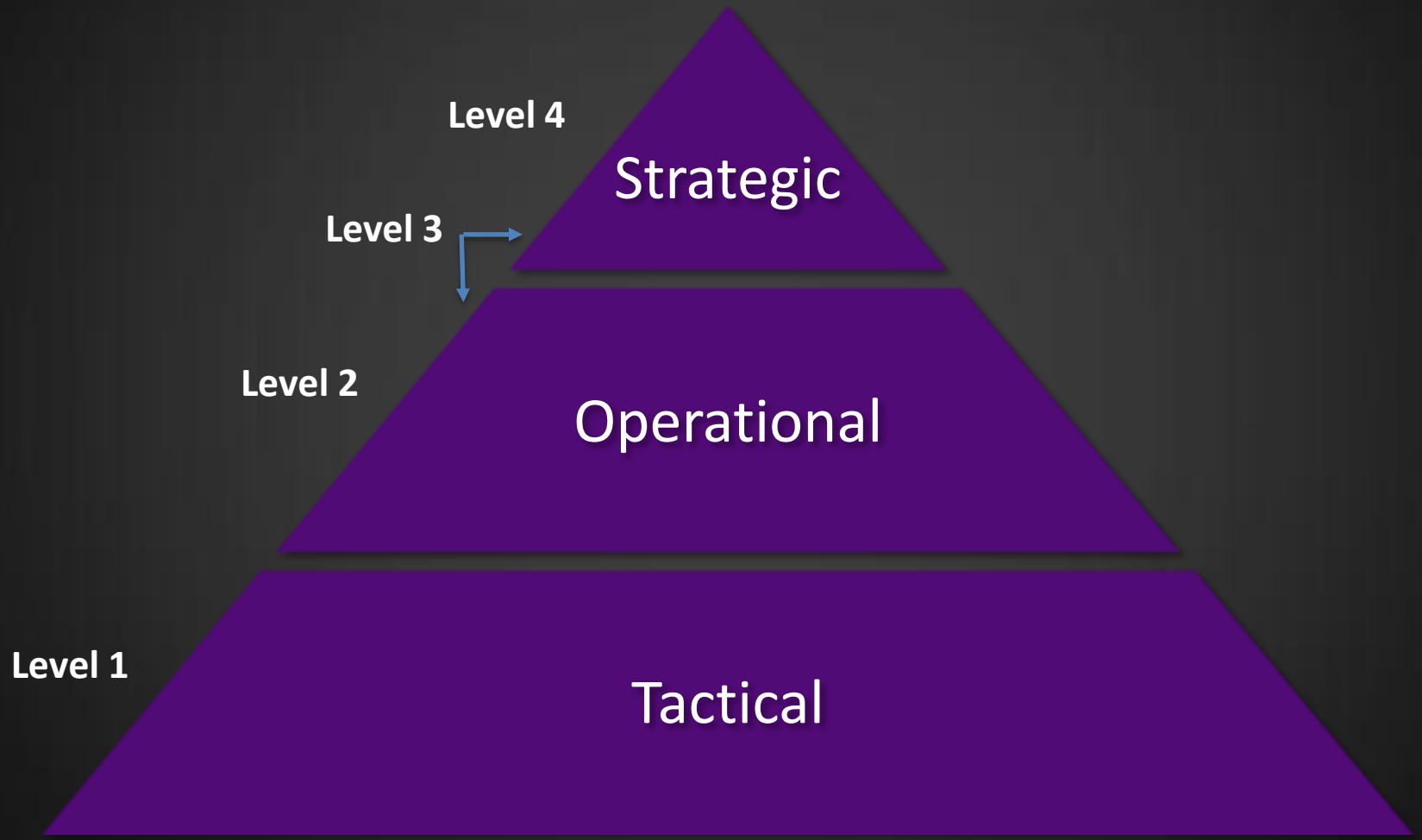
- Clearly conveys information to peers, supervisors and other stakeholders.
- Assists in preparation for meetings with regulatory agencies and other stakeholders.
- Assists in the preparation of briefings and other information documents.
- Communicates information on regulatory requirements to other departments and business units.
- Composes routine communications with regulators and other key stakeholders.

Sample Domain: Postapproval/Postmarket

Knowledge of requirements and processes to maintain a product on the market; reporting and surveillance.

Level 1	**Maintains, assists, tracks…**
Level 2	**Reviews, assures, submits, participates**
Level 3	**Develops, reviews, approves, adapts, understands**
Level 4	**Approves, integrates, leads, represents**

Progression of Competencies



Career Development Planning Process

Applying Framework to Career Development Planning for Organizations

The Development Planning Process

FOR EMPLOYEES

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PHASE 1 Preparation	**1. Assess current competencies:** *You and your manager assess your current level of competency against the core, functional and job-specific competencies in preparation for mapping out a development plan and determining where to focus your efforts* ❑ Review website for competency profiles and associated behavioral descriptions (RAPS.org/framework_whitepaper) ❑ Honestly assess yourself ❑ Identify gaps and strengths	**2. Determine development priorities:** *These priorities should reflect an effort to build on the strengths and address competency gaps* ❑ Reflect on and research development opportunities that will help you accomplish your objectives
PHASE 2 Holding the Development Discussion	**3. Identify development actions:** *These should be tailored to your needs and learning style* ❑ Meet with your manager and discuss how to focus your development plan ❑ Be open and receptive to feedback ❑ Become aware by listening and being open to new information ❑ Take ownership by asking questions to clarify your understanding of what needs to be done ❑ Discuss draft development objectives; understand parameters that relate to cost, time, etc. ❑ Become a stakeholder in your own development by researching cost effective learning strategies ❑ Set a date with your manager to secure final approval of your development plan	**4. Prepare a development plan:** *Identify specific action steps and a timetable for completion; include specifics regarding resource needs and the involvement of others* ❑ Refine the draft development objectives you created with your manager ❑ Articulate development objectives that include variety, intensity, diversity and adversity ❑ Be open to new ways of learning ❑ Choose learning opportunities that match the development need and fit your learning style ❑ Consider the parameters your manager explained with regard to cost, time, etc.
PHASE 3 Drafting and Implementing the Development Plan	**5. Implement and monitor the development plan:** *Periodic reviews against progress will ensure you stay on track* ❑ Ensure you have regular meetings with your manager to review progress on your plan ❑ Ask for feedback from various sources (e.g., manager, peers, customers, etc.) ❑ Challenge yourself to stretch beyond your comfort zone ❑ Honestly evaluate your own progress to goal and talk to your manager about it ❑ Find opportunities to practice new learnings ❑ Participate in two-way communication	**6. Coach for success:** *Encourage your manager to provide feedback about your progress against goals* ❑ Ask for help

Applying Framework to Career Development Planning for Individuals

The Development Planning Process

FOR MANAGERS

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PHASE 1 Preparation	**1. Assess current competencies:** *Assess your employee's current level of competency against core, functional and job-specific competencies in preparation for mapping out a development plan and determining where to focus efforts* ❑ Review website for competency profiles and associated behavioral descriptions (RAPS.org/framework_whitepaper) ❑ Honestly assess the employee against each competency identified for the job ❑ Identify the employee's gaps and strengths ❑ Schedule development discussions with all employees	**2. Determine development priorities:** *These priorities should reflect an effort to build on the employee's strengths and address competency gaps* ❑ Reflect on employee's potential development plan ❑ Consider strategies that can be utilized to implement the plan
PHASE 2 Holding the Development Discussion	**3. Identify development actions:** *These should be tailored to the employee's needs and learning style* ❑ Meet with each employee to discuss the development plan ❑ Listen to the employee's observations and share your point of view ❑ Explain your conclusions and give specific behavioral examples ❑ Recognize areas of strength and be clear if a development need is critical ❑ For each development opportunity, discuss what you expect to change, why a change is needed and what the timeline is to accomplish it ❑ Answer tough questions candidly ❑ Focus the development strategy on a maximum of 3 - 5 competencies ❑ Help the employee draft development objectives that support competency development ❑ Make suggestions about potential learning opportunities that help to focus on development; define parameters that relate to cost, time, etc. ❑ Confirm understanding and be available for follow up	**4. Prepare a development plan:** *Identify specific action steps and a timetable for its completion; include specifics regarding resource needs and the involvement of others* ❑ Provide coaching to the employee as he/she creates the development plan ❑ Ensure the plan is realistic and includes a strategy for follow up ❑ Approve the final development plan ❑ Encourage a variety of learning opportunities (e.g., on-the-job training, mentoring, seminars, etc.) to maximize results ❑ Coach the employee on using new channels of learning and ask tough questions to promote learning
PHASE 3 Drafting and Implementing the Development Plan	**5. Implement and monitor the development plan:** *Periodic reviews against progress will ensure the employee stays on track* ❑ Help build a forum to practice and apply learnings ❑ Look for evidence that application of learning has contributed to enhanced business results ❑ Give regular feedback ❑ Recognize improvements in competency development ❑ Be open to two-way communication	**6. Coach for success:** *Recognize progress against goals* ❑ Be dedicated to your role as coach, teacher, trainer and mentor

Career Development Points To Consider

- Multiple paths into the profession
- Company size/structure impact roles
- Individuals and organizations need a destination and a plan
- Career/professional development are investments for the future
- Regulatory knowledge and business-communication skills are critical

Regulatory Affairs Certification (RAC)

RAC is the only accredited post-academic credential for regulatory professionals

- Exam-based; developed from extensive job analysis studies
- 7,000 professionals have earned the RAC credential
- RAC program is guided by RAC Board and exam committees
- Spring/autumn testing windows

Four RAC Exams

RAC US	RAC EU	RAC CAN	RAC Global
▪ Regulatory functions throughout product lifecycle; covers all regulated health products ▪ Regulatory knowledge, critical thinking and analysis			
FDA regulations and knowledge of other agencies involved in health products in US	European regulations and guidances from the European Commission, EMA, Competent Authorities	Health Canada regulations	International standards and guidelines (i.e., ICH, IMDRF, WHO and ISO)
Regulatory professionals submitting to, or involved with, regulatory authorities in the US	Regulatory professionals submitting to, or involved with, regulatory authorities in the EU	Regulatory professionals submitting to, or involved with, regulatory authorities in Canada	All regulatory professionals, especially those in Asia, Latin America and other locations not submitting to US, EU or Canada

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