Session 6: Regulatory Competency Framework

How to build competency for Applicant

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26 June 2018

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- Regulatory competency: GSubP
- Regulatory competency building approach

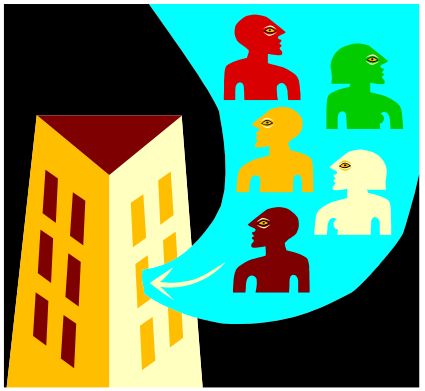
Regulatory – A Liaison between Company & Authorities

company

R&D

Supply

Marketing



Corporate function
(finance, legal, GM etc.)

- Regulatory communicates the regulations and regulatory requirements to the Company to formulate the regulatory strategy and registration plan for projects.
- Regulatory guides the Company on regulatory trends, and anticipates and addresses potential issues & opportunities.

Regulatory Affairs

Expert in *scientific communication* to external authorities and *regulatory communication* to company

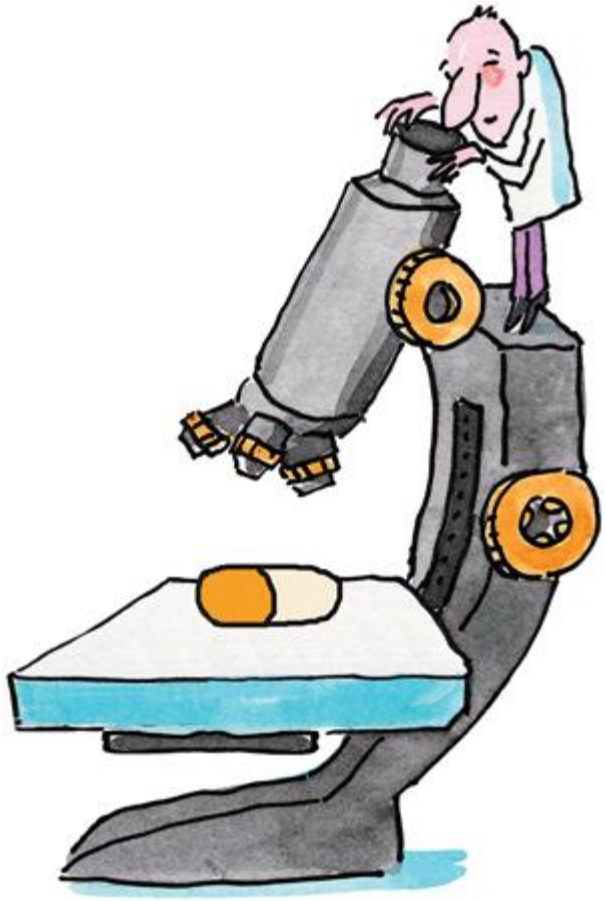
Government Agencies

- Regulatory presents Company information on product efficacy / safety / quality to government agencies & external groups
- Regulatory influences authorities and NGOs for a scientific/risk-based regulatory environment and to defend/protect the interests of the company

What is role of Regulatory Affairs (RA) in the industry?

- *Healthcare industry (both importer & manufacturer)* must supply the good quality, efficacious and safe healthcare products, and comply to the Health Authority (HA) regulations.

- *RA in healthcare industry* helps assure the HA rule/regulations are fully implemented in their operation. RA also help companies obtaining the necessary regulatory compliance permits & licenses.



Introduction to Regulatory function in *R&D and commercialization*

Lab to Launch / Bench to Bed

R&D Pipeline Cross Function Participants

Reference: Oracle Whitepaper on Product Lifecycle Management for the Pharmaceutical Industry,, Todd Hein, Oracle LifeScience

Regulatory competency

Good Submission Practice

Regulatory Affairs profession - Applicants

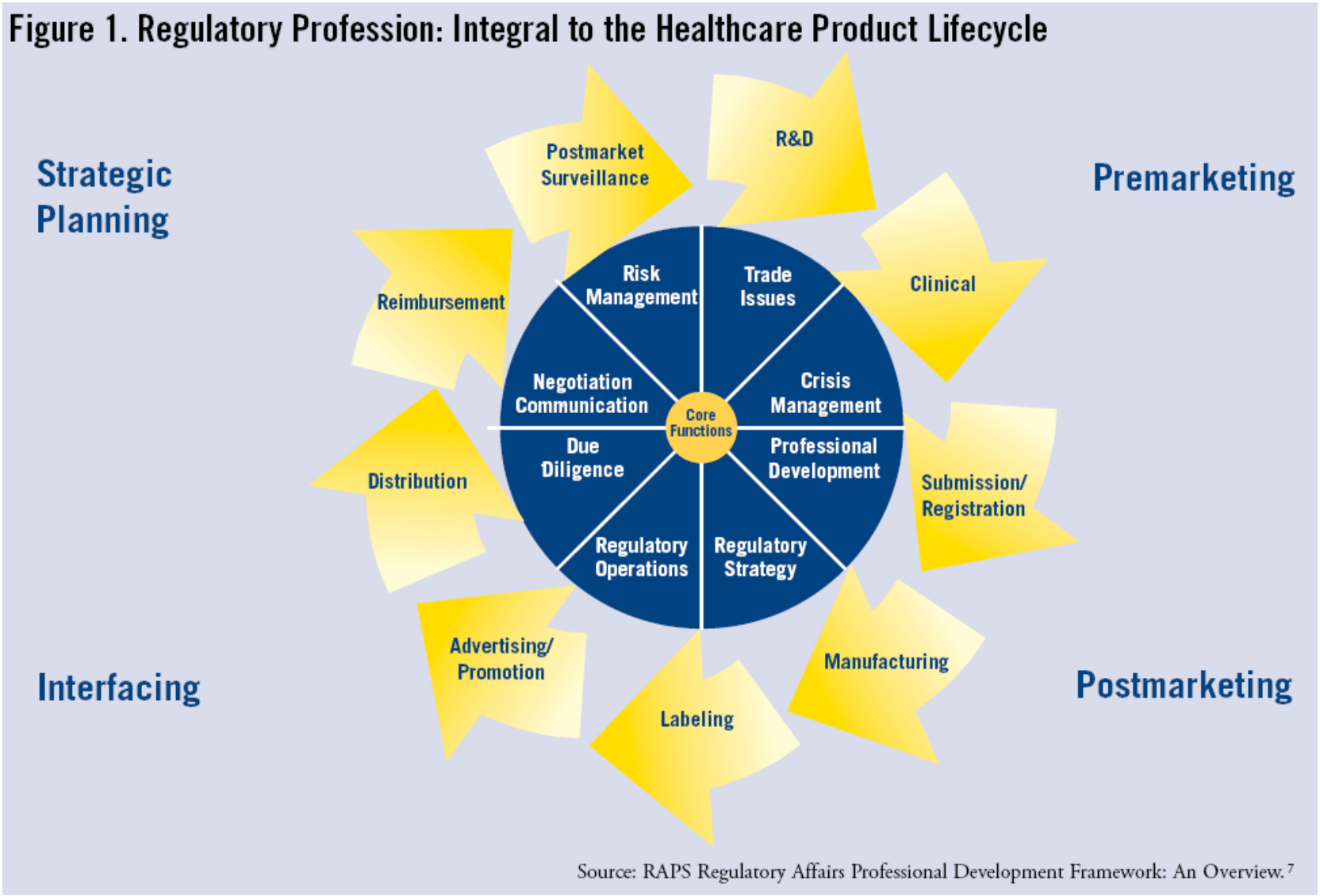
The person or company who submits

- an application for marketing authorization of a new medical product,
- an update to an existing marketing authorization or
- a variation to an existing marketing authorization.

(as defined in WHO GRevP guidelines 1)

RA in Life-cycle of Pharmaceutical product

Figure 1. Regulatory Profession: Integral to the Healthcare Product Lifecycle



Source: RAPS Regulatory Affairs Professional Development Framework: An Overview.[7]

Regulatory Affairs Pharmacy: Overall competency

SCIENCES

Quality
- Pharmaceutics
- Material sciences
- Analytical chemistry
- Medicinal chemistry
- Biopharmaceutics

Efficacy
- Pharmacology
- Clinical sciences
- Pharmacoeconomics
- Behavior sciences

Safety
- Toxicology
- Public health policy
- Pharmacoepidemiology

etc.

PRACTICES

- **Good Submission Practices**
- **FDA laws/regulations**
- **Pharmaceutical business**
- **Project Management**
- **Scientific Communication**
- **Professional standard**
- **Ethical standard**

GSubP– Competency for Applicants

SCIENCES

Scientific knowledge and expertise

Good understanding of up-to-date regulations

Other hard and soft skills

Integrity and reliability

PRACTICES

Core competency-1

Scientific knowledge and expertise

- Professional **knowledge and expertise** that relate to the product **safety, efficacy and quality**.
- **Application** of each field of scientific knowledge
- Understanding on **risk-benefit analysis**
- **Critical thinking methodology**
- Critical for the authors and reviewers of technical documents in submission dossier.
- Excellence in writing skills

Core competency-2

Good understanding of up-to-date regulations

- Knowledge on the **latest regulatory environment**, through
  - Regular monitor regulatory authorities' website and check updated news, notices or highlights.
  - Subscribe to a mail delivery service provided by the review authorities
- Understand **content** of regulation, as well as **background** & its **implication/impact**
- **Study** published regulations, technical guidelines, notices, Q&A documents etc.
- Attend **training programs** provided by the regulatory authorities, industry associations or other third parties.

Core competency-3

Other hard and soft skills

- Planning and project management
- Medical and technical writing
- Technical skills for electronic submission (as necessary)
- Problem-solving
- Communication

Core competency-4

Integrity and reliability

- Approach the process with **honesty, integrity and reliability**
- Not to jeopardize the trust/confidence of the regulatory authorities and other stakeholders.

Competency building approach

- Define the competency **into "description, objective and measurable competency"**
- Define the **level of competency** from basic to advance
- Use **multiple tools/processes** to help build the competency

1. Regulatory Strategy

Ability to develop clear, sound regulatory strategies, which are aligned with Brand Footprint and Category Strategy
Utilises knowledge of the regulations to gain a competitor advantage, improve speed to market and ensure Global regulatory compliance.

	Limited	Basic	Proficient	Advanced	Coach
Strategic thinking	Executes regulatory strategies and programs developed by others	Participates in the development and execution of regulatory project strategies	Leads development and execution of regulatory strategies demonstrating a solid understanding of category strategies; Ensures that all regulatory activities are aligned with brand footprints and category strategy	Leads the development of regulatory strategies and programs (Short, medium and long term) aligned to brand footprint and Global Category strategy	Coaches others on the development of short, medium and long term regulatory strategies and programs, aligned with Global Category Strategy
Regulatory Knowledge	Interprets and applies regulations and legislative information to product development plans and business initiatives.	Sources relevant regulatory and legislative information in order to develop regulatory project strategies for new product development plans and business activities	Proactively analyses new regulations and trends and builds on this to drive delivery of regulatory strategies within assigned area	Proactively analyses new regulations, trends, and builds on this to drive delivery of regulatory strategies cross brand/function. Continues to improve processes to deliver the most efficient and compliant regulatory strategies in line with these new regulations. Propose best practices for setting standards to identify regulatory insights	Helps others set and establish standards of best practice for identifying regulatory insights and translating these into clear focused set of actions.
Networking	Limited local network of external contacts (e.g. trade associations, local regulatory, regulatory authorities, consultants etc) to assist in the interpretation of regulations and legislation	Maintains relationships with a local network of external contacts to better understand the impact that regulations/legislative activity has on Regulatory project strategies	Builds and maintains a robust regional network of external contacts to work with on developing regulatory strategies. Searches for and recommending external providers (e.g. consultants)	Proactively builds and maintains an extensive Regional/Global network of external contacts to work with to address any gaps with regulatory strategies. Negotiates and closes the deal with selected external providers	Coaches on methods of assessment / selection for key external providers, as well as how to further develop and effectively manage a strong network of external providers.
Risk management	Identifies any potential regulatory risks (including any timeline delays) on regulatory strategies to regulatory manager	Identifies any potential regulatory risks, along with recommendations to mitigate risk and agrees strategy with regulatory manager for managing expectations within the business.	Challenges status quo and continuously looks for ways to implement category initiatives. Willingly takes risks associated with innovations and seeks alternative regulatory approaches when discussing strategies. Effectively manages expectations with key stakeholders in the business.	Manages confrontation or issues with a high level of sensitivity and control. Leads others in anticipating regulatory issues, managing and communicating risk.	Coaches on methods for managing risk and communicating to different stakeholders within the business whilst still maintaining a good working relationship.

5. Regulatory Project Management

Ability to manage complex and multifunctional projects and regulatory issues in ways that optimise the efficiency, quality, regulatory compliance and speed of delivery contributing to the execution of RB projects.

	Limited	Basic	Proficient	Advanced	Coach
Project Strategy	Primarily focused on day-to-day operations following assigned action plan	Links own action plan in line with project strategy/business needs	Assists in the development of the brand Portfolio and Regulatory Strategy for own category/function in line with Brand Plans and project targets.	Leads in the development of the brand Portfolio and Regulatory Strategy for own category/function in line with Brand Plans and project targets.	Supports others in developing an integrated cross-functional business and regulatory strategy and contingencies aligned with the Global business Strategy.
Decision Making	Relies mainly on experience and guidance of others for decision- making and execution	As part of a project team understands business targets and feeds in regulatory steps and timings to the project team that contributes to decision making and project planning.	Makes decisions and takes actions on strategic issues, clarifies and communicates them to the project team and manages execution of the actions.	Balances gut-feel with an ability to convert and translate data into a wide range of actionable proposals / recommendations. Uses best practices to access data and conduct sophisticated analyses that support arguments and decisions.	Coaches and leads others in the use of advanced analysis methods and understanding of relevant trends, around business targets and other key functional measures.
Project Management	Participates on projects and is aware of project objectives and benefits and is able to answer queries for area of responsibility.	Runs approved projects, delivers against targets and communicates risks and progress of the project with guidance.	Accurately assesses and forecasts regulatory issues and establishes contingency plans and risk management.	Considers wider and longer-term business goals. Anticipates future trends and identifies opportunities and risks associated with acting (or not acting) on them. Leads complex, multiple or cross-functional projects ensuring execution using a wide range of skills and experiences.	Proactively helps and advises others in accurately assessing and managing risks and is consulted by others for input with regard to risk management. Coaches and supports others in project management, systems, methods and best practices, including contingency planning. Participates in re-defining RB Global Project Management methods and systems to increase effectiveness of overall project delivery.
Project Teamwork	Participates effectively within project teams carrying out assigned tasks.	Contributes to project decisions and progress	Work within project team to achieve project targets, balance resources, ensures high quality performance and speed to market.	Inspires project team members to take ownership and deliver project results against business objectives.	Coaches others in the ability to inspire the team, take ownership, balance resources and prioritise to deliver against business objectives.
Time Management	Can work to defined timings and deadlines to ensure project completion	Can propose appropriate timelines for projects from a regulatory perspective, taking into account data requirements, but still works to defined deadline	Proposes and influences realistic project timelines, taking into account category priorities, regulatory timings.	Can effectively accept or reject business proposals, with a sound justification, based on category priority, regulatory timings, compliance and available resource.	Coaches others to propose realistic regulatory timings to align business expectations, available resource and category priorities to ensure compliance.

Example of RA competency description & level

Scope of Regulatory Affairs Practice

Vice President

Director

Manager

Associate

Postmarket (post-license)
Labeling
Advertising and promotion
Manufacturing
GMP, QA, QC
Environmental
Audit
Compliance
Postmarket surveillance
Distribution
Reimbursement

Premarket
Research and development
Preclinical
Clinical/GCP
Submissions

Regulatory Strategy
Including regulatory intelligence

Business
Corporate management
Business development
Finance
Human resources
Government affairs
Legal
Negotiations

Product lifecycle management

Related to all areas
Crisis management Risk management

Ref: RAPS Special Report *June 2009:* The Rise of Business and Strategy in Regulatory Practice

Skill & expertise developments

RA Level I

Professionals who are new or relatively new to the profession with limited or no regulatory affairs knowledge *(Example job titles: coordinator and some associate positions)*

- understand specific aspects of the healthcare product arena
- develop basic knowledge and understanding of the regulatory and legal frameworks, regulatory requirements, legislation, processes and procedures.
- possess skills such as project management, writing, coordination, and interpersonal and communication skills.
- coordinate and support technical and scientific regulatory activities.
- less focus on technical skills and more focus on project coordination and support.

Skill & expertise developments

RA Level II

Professionals who develop and expand upon an integrated understanding of regulatory affairs as it applies throughout the product lifecycle. Strong emphasis on technical aspects of the profession, combined with scientific understanding and strong project management. *(Example job titles: some associate positions, specialist, and some assistant manager and manager positions)*

- 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.
- 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, post-marketing surveillance/vigilance; and distribution.
- Focus on hands-on training to strengthen and develop new skills and knowledge.

Skill & expertise developments

RA 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. *(Example job titles: manager, associate director, director)*

- Individuals at this level have strong technical and management skills and are actively engaged in regulatory strategy and operations.
- Engaged in activities spanning the product lifecycle and are involved in business/ organizational activities, management and strategy.
- 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.

Skill & expertise developments

RA Level IV

Level IV professionals assume the strategic lead representing the regulatory perspective while developing new approaches for business objectives. (*Example job titles: may include directors in some organizations, vice president, executive director, chief regulatory officer)*

- 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.
- Responsible in strategic planning and interfacing throughout the product lifecycle, both within the organization and with diverse external groups.
- Strong and extensive understanding of the role of the profession in the product lifecycle and the dynamics of regulatory processes.
- Engaged in policy development within their organizations and with external groups.
- Leaders and mentors within their organization and for the profession.
- Able to work effectively in multinational/multicultural environments.

Competency building – why we need this?

- To acquire sufficient core competencies and strengthen skills and capacity.
- To deepen their own scientific, technical and regulatory knowledge and expertise.
- To acquire necessary skills and competence
- To establish good documentation practice

Training tools & processes

External sources:-

•training programs provided by regulatory authorities, industry associations and other third parties.

•periodical educational programs, workshops and training sessions for applicants.

•HA’s briefing sessions for applicants when they release a new regulation or guideline, and prepare Q&A documents.

Internal sources:-

•in-house training, self-training and on-the-job training in applicants’ organization

•Good practices sharing (past submissions), in the form of manuals, SOP, database or any other appropriate tools.

Conclusion

- Regulatory affairs plays important role in GSubP to drive the efficient registration process
- RA competency in GSubP would require both scientific and management skills
- RA competency building can be achieved through the well defined competency & level planning, along with the use of multiple tools/processes.

Questions & Answers