

# INTRODUCTION TO RA

**CAPRA**  
**ACPR**



Canadian  
Association of  
Professionals  
in Regulatory  
Affairs

Association  
canadienne des  
professionnels en  
réglementation

# OVERVIEW

- What is Regulatory Affairs ?
- Other Functional Areas of Interest
- Who are Regulatory Professionals?
- Why consider a career in Regulatory Affairs?
- The future of Regulatory Affairs



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# Why Regulatory Affairs?

- Medicinal Products are a very specialized form of consumer product
- They must be safe, effective and suitable for their intended purpose
- Pharmaceutical manufacturers must satisfy themselves, the regulatory authorities, the medical profession and patients that their products are safe and suitable
- Canadian pharmaceutical industry is regulated by Health Canada

# What is Regulatory Affairs?

- Profession within regulated industries, such as pharmaceuticals, biopharmaceuticals, medical devices, cosmetics and consumer health, natural health and veterinary products
- Regulatory Affairs is the department within the company that interacts with the government authorities who regulate the activities of the company (e.g. Health Canada)

# What does a Regulatory Professional Do?

- Keep track of changing legislation in regions where the company distributes its products
- Interpret and apply regulations
- Advise internal colleagues on legal and scientific requirements
- Develop and implement regulatory strategies
- Collect, collate and evaluate scientific data
- Prepare submissions to regulatory agencies such as Health Canada, FDA (US), EMA (Europe) and in other jurisdictions
- Participate in product development programs to ensure adherence to international regulations and guidelines

# Other Functional Areas of Interest

- RA professionals interact with numerous functional areas:
  - Pre-Clinical Research
    - Pharmacology and Toxicology testing to evaluate new drug candidates
  - Clinical Research
    - Conduct of clinical studies, data collection, statistical analysis, report writing
  - Manufacturing
    - High levels of controls for production of safe and efficacious products
  - Quality Control
    - Analytical testing of all product lots for purity, potency, safety, quality
  - Quality Assurance
    - Oversight of operations related to failure investigations, auditing, recalls, complaints, documentation management

# Other Functional Areas of Interest

- RA professionals interact with numerous functional areas:
  - Sales and Marketing
    - Review and approval of advertising materials and communications for new product launches
  - Legal (Intellectual Property)
  - Project Management Team
    - Managing complex, multi-functional projects

# Why is Regulatory Affairs Important?

- RA is the point of contact between the company and regulatory authorities
  - Attitudes and actions of RA contribute to how the health authorities perceive the company overall
- RA professionals play a critical role in the reduction of time taken for a product to reach the market, and take steps to ensure the products remain on the market
  - Contributes to company success
  - Economically important for the company



# Who are Regulatory Professionals

- RA professionals are generally graduates of scientific disciplines
- Skill set of a successful RA professional:
  - project management
  - communication skills
  - negotiation skills
  - analytical skills
  - presentation skills
  - Strong ethics / integrity
  - Good judgement

# Why Consider a Career in Regulatory Affairs?

- Environment of continuous learning and growth (e.g., changing laws and science)
- Work in a business sector that is involved in the evolution of scientific knowledge
- Work with colleagues in a variety of functional areas such as pharmacologists, chemists, medical doctors, engineers, lawyers
- Work in an area that can influence health and well-being of millions of people

# The Future of Health Care

- Aging population
- People living longer lives
- Increased consumer demand for medical interventions due to availability of information (internet)

# The Future of Regulatory Affairs

- New technologies will drive industry growth
  - Stem cell therapies
  - Nanotechnology
  - Personalized medicine
    - will allow medicines to be tailored to patients' needs based on their genetic profile
  - Gene therapies
  - Increased diagnostic capabilities