Associate Director, Regulatory Affairs

Being Here Matters!

Are you ready to make a real difference in the lives of patients?

We at Gilead are passionate about advancing therapeutics and improving lives. At Gilead you are a part of a rapidly growing science-driven organization, working together to revolutionize healthcare by bringing innovative, urgently needed medicines to patients living with life-threatening diseases. We are energetic leaders and strategic entrepreneurs going above and beyond for patients, inspired by the opportunity to address unmet medical needs. Now you have the chance to join us and be a part of this change!

As an ***Associate Director, Regulatory Affairs*** in Mississauga, Canada, you will be reporting to the Senior Director (Regulatory Affairs Head) and be a key member of the leadership team for the Canadian department. You will be a core member of a game changing team that challenges risks by its critical thinking and passion for deep diving. As an expert in the subject matter and as a key leader in the department, you will represent Regulatory Affairs at internal and external meetings both locally and at a global level. Our diversity of thought and in culture will broaden your leadership skills and expand your outreach in several therapeutic areas making a real difference in the lives of patients.

The Job Overview and Your Key Responsibilities

The Associate Director, Regulatory Affairs is a leadership position and will be a key cross functional business partner, responsible for (or have oversight of) multiple therapeutic areas which will likely include oncology, cell therapy, HIV/AIDS and Inflammation. In this position you will ensure that Gilead complies with Canada's applicable legislations and regulations linked to the local license as Marketing Authorization Holder (MAH) or as local legal representative of the MAH. Also you will ensure that the medicinal products in your responsibility can be developed, authorized and maintained on the Canadian market from a regulatory perspective.

Job Responsibilities

- Provides and contributes to the vision and direction, as well as sets clear goals and objectives, for Regulatory Affairs Canada in line with the broader Global Regulatory Affairs organization and the local Gilead Canada Affiliate
- Provide support to Regulatory Affairs Head on the local Affiliate leadership team providing cross functional support and strategic advice
- Ensure that Gilead fulfills all relevant requirements linked to the MA / local license as MAH or as local legal representative of the MAH for the Canadian Affiliate
- Crisis management functional lead in the Affiliate or support to functional lead and leadership team
- Develops or contributes to resource and budget planning and utilization
- Lead or support communicating important changes to the local Regulatory function
- Manages a team of multiple Regulatory professionals and leads Regulatory activities for responsible therapeutic areas. Responsible for certain RA teams deliverables, professional development and contributing to succession plans for critical roles
- Leads the preparation of challenging regulatory submissions/matters (initial NDSs, line extensions, and risk management/minimisation activities) for products in responsible therapeutic areas to Health Canada and leads

the interaction, negotiations and communication internally and externally, co-ordinates cross-functional responses and act as the main point of contact for Health Canada
- Leads or supports Canadian scientific advice and / or pre-submission meeting preparation and follow-up
- Leads or provides Affiliate input to the International and global regulatory strategy, as appropriate, including input into clinical development programmes
- Ensures compliance with Canadian law and regulation and consistency with applicable global procedural documents
- Initiates local improvements and contributes to local and/or global process improvements which have a significant impact for Regulatory Affairs and other departments, assesses proposed changes to local procedural documents, sharing of best practice and impact on existing processes
- Responsible for promotional material review and approval for products in responsible therapeutic areas, certifies materials where appropriate
- Leads risk assessments on major local regulatory issues and changes, and develops mitigation strategies
- A regulatory expert in updating and preparing the Company for major changes in regulatory legislation and competitor information in Canada, contributes to guideline and regulation development and develops strategies to optimize the outcome
- Leads and/or is an ambassador for Regulatory Affairs at internal and external meetings or working parties building recognition as a thought leader
- Mentoring, training and coaching regulatory and non-regulatory staff

Your Specific education and experience requirements:

<u>Knowledge & Skills</u>

- Leadership skills, with vision and direction setting, showing the ability to influence externally, cross-functionally and within global Regulatory Affairs
- Enthusiasm and desire to gain diverse experience, influence and actively participate in important initiatives and process improvements at both the local affiliate and global level.
- Extensive experience working with Health Canada at a senior level
- Capable of developing and implementing regulatory strategies and/or managing complex discussions with Health Canada
- Experience and knowledge in oncology, cell therapy, HIV, inflammation are desired. Experience with CMC a plus.
- Experienced leader of projects and teams
- Strong interest and experience in people management and development
- Ability to prioritize, influence, negotiate and make decisions
- Excellent verbal and written English language skills, organizational skills and interpersonal communication skills.

<u>Education & Experience</u>

- 12+ years of experience in Regulatory Affairs with a BS/BA degree or 10+ years' experience in Regulatory Affairs with an advanced degree in a scientific field.
- BS/ BA required. Advance degree in scientific field is desired but not required.
- Excellent knowledge and proven experience in understanding and implementing regulatory requirements in Pharmaceutical / Biotech Industry, including ICH requirements and Health Canada requirements and have an understanding of current trends in Canada.
- Experienced in developing and implementing complex regulatory strategy and managing challenging negotiations with Health Canada
- Knowledge of quality assurance, promotional and non-promotional review as well as pharmacovigilance and market access
- Experienced in working and leading cross-functional project teams

- Excellent working knowledge regarding Health Canada and Canadian Trade Associations. Excellent knowledge of developing trends in the local rules and regulations and the potential impact to the organisation

Apply Now!

We’re an equal opportunity employer. Apply online today at

https://gilead.wd1.myworkdayjobs.com/gileadcareers/job/Ontario/Associate-Director--Regulatory-Affairs_R0005905