

REGULATORY AFFAIRS MANAGER, SCIENTIFIC AFFAIRS (Contract, 14 months)

Division:

Scientific Affairs

Reporting to:

Director, Scientific Affairs

Location:

Mississauga Ontario

Only local candidates will be considered.

Only individuals with management or those who led a group will be seriously considered.

MAJOR PURPOSE:

Regulatory leader focused on strategic and operational support to the Canadian GSK CH business. Oversee the development and responsibilities of direct reports. Provide input as a member of the Scientific Affairs Leadership Team. Initiate business and process improvements. Identify and act on new regulatory and environmental trends. Provide creative and strategic regulatory vision to support new products launches. Negotiate submission approvals with regulatory bodies.

PRIMARY RESPONSIBILITIES:

Dynamic and motivated individual to lead regulatory support for projects/products in Consumer Healthcare.

- Serve as the primary regulatory contact for specific projects and/or program related activities;
- Serve as regulatory partner for business team;
- Manage direct reports;
- Contribute to the assessment of new innovation projects and exploratory product development briefs;
- Formulate regulatory strategies designed to minimize time for development and regulatory approval and optimize competitive positioning and global opportunities;
- Compile and submit quality regulatory dossiers in line with business plans and timing needs;
- Negotiate directly with regulatory agencies as necessary in relation to the development and marketing of products;
- Collaborate with key cross-functional team members to meet or beat all project goals;
- Review and approve all labeling, promotion, advertising, change controls, etc. for products;
- Monitor, analyze and advise the GSK business on existing and emerging global regulatory trends and requirements. Balance ideas and practices against regulatory risks;
- Participate in trade association and professional society activities, such as RAPS, CHPCanada, etc., where appropriate;
- Participate in Departmental Senior Management team activities, as appropriate;

- Develops regulatory strategies for rapid approvals with optimal labeling for products;
- Ensures compliance with HPFB requirements and alignment with business needs.
- Builds relationships with and influences Health Canada contacts to improve GSK submission approval times, achieve competitive labeling and resolve product related issues.
- Communicates with and influences multiple local and global functions, including local Executive team members, to convey product and submission strategies, timelines and risks
- Evaluates and assigns regulatory risk associated with issues and activities relating to their products

QUALIFICATIONS REQUIRED:

- B.Sc. / BA in a scientific discipline required. RAC preferred
- At least 5 years experience within regulatory affairs
- Led or managed a group of people
- Background in consumer products is preferred; Rx to OTC switch, natural health product experience preferred
- Excellent knowledge, understanding and ability to interpret current global Regulatory Affairs environment, with detailed knowledge of Canadian regulatory affairs and experience with various submission types (NDS, ANDS, SNDS, NPN, Medical Device and Establishment Licence)
- Extensive experience in submission preparation and a proven track record of success in regulatory affairs.
- Must possess a thorough understanding of the Canadian Food & Drug Regulations, relevant guidelines and policies for the lifecycle management for products.
- Highly innovative (strategic and functional) and creative problem solver who can apply continuous improvement techniques to gain efficiencies in submission preparation and product approval process.
- Excellent interpersonal, verbal and written communication skills
- Demonstrated strength in facilitating projects and multiple tasks
- Ability to negotiate and influence positively at multiple levels, internal and external
- Strong PC skills required
- Awareness and ability to work within areas of cultural difference
- Ability to prioritize personal and team activities and issues.

TO APPLY:

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