Position: **Regulatory Affairs Project Manager, Animal Health**
Start Date: **March 1, 2019**
Type: **1-year contract (full time)**
Location: **Mississauga, ON**

Position purpose:

- Develop and lead regulatory strategies related to pharmaceutical and biologic products as well as pesticides for Bayer Animal Health in accordance with policies, procedures, and federal legislation.
- Develop and lead key local submission strategies across Therapeutic Areas in role as local RA expert. Represent Canada as RA expert on global cross-functional teams. Lead local functions in the development and execution of regulatory strategies for registration and maintenance of products.

Major tasks and responsibilities of position:

- Represents Regulatory Affairs (RA) in product development teams.
- Responsibility for the regulatory strategy for Animal Health products in close cooperation with the relevant global and regional RA functions, Bayer Crop Science, Veterinary Scientific Affairs, Quality Assurance, Marketing and Legal, to ensure early identification of major regulatory hurdles and issues, regulatory guidelines and legal requirements.
- Responsibility for final content of submissions for assigned products to necessary authorities, including responses to authority questions.
- Responsibility for the change management for marketed products, which includes tracking of product changes and processing of requests for related documentation (evaluation, consolidation, prioritization and review), responsibility for coordination of responses to health authority questions, and for implementation of product changes after approvals.
- Liaises closely with designated key contact at Bayer Crop Science for PMRA-related submissions and maintenance activities.
- Ensures adequate surveillance of the animal health regulatory environment; anticipates, and influences changes in this environment globally.

Value added to the success of the company:

- Independently manage all Regulatory activities for Bayer's Animal Health business in Canada.
- Independently lead the preparation, negotiation and finalization of high quality and timely regulatory approvals, including Level III and IV changes, Notifiable Changes, Supplemental New Drug Submissions and New Drug Submissions.
- Lead and develop local procedures and processes to ensure consistency of regulatory strategies and content across Therapeutic Areas as required.
- Implement and/or manage labeling changes and quality change management activities in cooperation with global RA staff.
- Identify major clinical, technical or operational issues affecting the success of filing, approvals and maintenance within a specific product portfolio.
- Continually enhance interactions and relationships with Canadian Health Authorities and other external stakeholders through effective collaboration and communication.
- Request and conduct Health Authority meetings as needed during the drug development and filing processes.

- Partner and lead Regulatory strategies with Veterinary Scientific Affairs, Marketing, Legal, Quality Assurance and Global Regulatory Affairs to support Bayer Animal Health's products.
- Lead cross-functional submission and negotiation teams.
- Participate as the Canadian representative on global cross-functional and/or regulatory strategy teams
- Lead the regulatory review of promotional material, press releases and regulatory labeling.
- Lead the development or maintenance of procedures and processes to ensure compliance with federal legislation, and other applicable industry standards, in addition to efficiency improvements.
- Perform and manage other Regulatory Affairs duties for Bayer Animal Health as required.
- Maintain Canadian Regulatory compliance to relevant Bayer SOPs, OIs or other Bayer or Health Canada legislation, regulation, policy or guidance related documentation.
- Maintenance of local or global quality systems including archiving, contact reporting, tracking of documents submitted and input of information into databases.
- Opportunity to coach and mentor summer students to develop people management skills and/or may directly supervise temporary staff.

Qualifications:

- BSc (required) or MSc (preferred) in Pharmacy, Pharmacology, Chemistry, Biological Sciences, or equivalent.
- Minimum 4 years of progressive experience in Regulatory Affairs (experience in leading a major SNDS and/or NDS).
- Demonstrated knowledge and experience in Animal Health, encompassing Biologics, Pharmaceuticals and Pesticides seen as a plus.
- Demonstrated leadership potential.
- Bias for action and sound, independent decision-making.
- Excellent working knowledge of the Food & Drugs Act and Food and Drug Regulations.
- Strong analytical skills with the ability to assess scientific data.
- Proficient computer skills, including all MS Office applications.
- Proven oral and written communication skills.
- Ability to build and maintain strong and collaborative working relationships with internal and external contacts.
- Excellent organizational and negotiation skills.
- Ability to work independently and under pressure.
- Candidates must have demonstrated success in a regulatory environment (e.g. leading major submissions), and extensive knowledge of drug development (clinical studies, chemistry and manufacturing etc.) in the healthcare industry.

Bayer welcomes and encourages applications from people with disabilities. Candidates participating in our selection process, who need accommodation because of a disability or medical need, are encouraged to notify the Bayer representative that they will be meeting with so that appropriate arrangements can be made.

If interested in this opportunity, please apply to Shannon Cavanagh, Talent Acquisition via this link: https://career5.successfactors.eu/sfcareer/jobreqcareer?jobId=31649&company=C0003153479P&username=