Regulatory Affairs Project Manager

Mississauga

Title: **Regulatory Affairs Project Manager**
Department: Regulatory Affairs
Location: Mississauga Head Office

Objective:

Prepare and file submissions to obtain Health Canada approvals for assigned CTAs, NDSs and SNDSs, working closely with global regulatory counterparts and teams and local business teams. Lead adhoc Drug Regulatory Affairs (DRA) submission teams for major submission activities.

Responsibilities:

- Leads and manages assigned Regulatory Affairs projects for assigned products and/or other general regulatory operations, such as business processes, systems, records management, compliance, learning and development, etc.
- Responsible for regulatory strategic and operational management of a project or portfolio of projects for a variety of products in the assigned disease/therapeutic area or assigned markets.
- Plays a key role in ensuring Roche products achieve timely regulatory approval and broadest use possible.
- Supports or leads cross-functional regulatory affairs teams, and represents regulatory to other teams and functions.
- As applicable, provides input into cross-functional regulatory strategies and plans. Manages assigned projects from initiation through applicable maintenance phases, post-approvals, or hands-off projects after regulatory approvals are obtained.
- Ensures regulatory project deliverables are completed compliantly, accurately, thoroughly and in a high quality and timely manner.
- Where applicable, has interactions with health authorities and may advise others on health authority interactions.
- Keeps regulatory and other cross-functional management and regulatory project team members fully apprised of changes to strategies, timelines and risk assessment.
- Contributes to regulatory excellence by identifying opportunities, mitigating risks and supporting continuous improvement.

Qualifications:

- Bachelor's Degree with 5-8 years of work experience in regulatory affairs
- Proven experience in the pharmaceutical/biotech industry in Regulatory Affairs Department
- Strong interpersonal and communication skills
- Ability to communicate effectively at all levels of the organization and across cultures
- Ability to build an effective, collaborative team environment
- Strong problem-solving skills
- Strong project management and planning skills
- Strong presentation skills
- Thorough understanding of Health Canada regulations and guidelines

Qualified candidates are encouraged to submit cover letter and resume no later than October 23, 2019.

This position is not eligible for relocation support.

This position is open to applicants legally authorized to work in Canada.

NOTE: All employment is conditional upon the completing and obtaining a satisfactory background check, including educational, employment, references and criminal records (for which a pardon has not been granted) checks.

Roche is an equal opportunity employer and prohibits unlawful discrimination based upon any legally protected ground. Roche will make a good faith effort to accommodate the individual needs of applicants with disabilities in our recruitment process

AGENCY NOTICE: Please note that Roche Canada does not accept unsolicited resumes from recruiters or employment agencies. In the absence of a signed Services Agreement with agency/recruiter, Roche Canada will not consider or agree to payment of any referral compensation or recruiter fee. In the event a recruiter or agency submits a resume or candidate without a previously signed agreement, Roche Canada explicitly reserves the right to pursue and hire those candidate(s) without any financial obligation to the recruiter or agency.

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https://roche.wd3.myworkdayjobs.com/en-US/roche-ext/job/Mississauga/Regulatory-Affairs-Project-Manager_201910-128449/apply