**Role:** Regulatory Affairs CMC Specilaisr

**Location:** Toronto

**Job type:** Contract role: starting ASAP- running until December 2019

Full time hours, In house opportunity, Monday – Friday

**Overview:** The Regulatory Affairs CMC Manager is supporting the regulatory submission activities of the Canadian Regulatory Affairs CMC group for vaccines.

**Responsibilities:**

* Develops submission strategy and is responsible for managing all the regulatory CMC aspects throughout the life cycle of the assigned product/project.
* Authors the CMC sections (Modules 1, 2 and 3) of the regulatory submissions globally for line extension and quality changes for licensed vaccines.
* Participates in the development of the project timelines and ensures the deadline is met.
* Represents RA on R&D or Industrial Affairs teams when CMC expertise is required.
* Reviews the applicable regulatory guideline to ensure that the regulatory content of the assigned project is in compliance with it.
* Assures that submission dossier meets appropriate quality standards.
* In the process of authoring the submission, collaborates closely within Regulatory Affairs and with Subject Matter Experts from Industrial Affairs.
* Ensures that review comments are incorporated and that the documents are approved by the subject matter experts.
* Assures that technical and regulatory CMC issues are appropriately resolved with optimal solutions.
* Provides input for the project risk assessments and mitigation plans (as necessary).
* The RCM could be mandated to organize and lead contacts with regulatory agencies or third parties regarding CMC submissions and /or activities.

**Qualifications:**

* Minimum of a Bachelor’s Degree; advanced degree (Masters, PhD) in a science/health field, or equivalent preferred.
* Regulatory CMC submission writing experience, in biologics/vaccines.
* 2-5 years of direct Regulatory Affairs CMC experience in pharmaceutical industry.
* Requires knowledge and understanding of the main regulatory agencies regulations/guidelines.
* Demonstrated knowledge of microbiology, immunology, virology or bacteriology.
* Strong verbal and written communications, interpersonal and time management skills.
* Ability to work in group setting and independently; ability to adjust to changing priorities.
* Excellent attention to detail and strong organizational skills.
* Demonstrate initiative, some independent thinking and anticipatory foresight.