**Regulatory Affairs Associate**

**Pharmaceutical Company - London**

**BLES Biochemicals Inc.,** [**www.BLESbiochem.com**](http://www.blesbiochem.com)**,** seeks a Regulatory Affairs Associate for our London location. BLES Biochemicals Inc., manufactures and distributes a biologic drug product BLES® (bovine lipid extract surfactant). BLES® is a pulmonary surfactant used to treat premature infants suffering from neonatal respiratory distress syndrome (NRDS). BLES® is unique; there is no generic form of this product.

BLES Biochemicals Inc. is a privately-owned, Canadian-controlled pharmaceutical company. It is the market leader for pulmonary surfactant in Canada.

**The Regulatory Affairs Associate’s responsibilities include:**

* Assist in preparation of submissions for international markets and monitor submission progress.
* Ensure post-approval regulatory compliance in international markets and liaise with external partners.
* Obtain regulatory documents and ensure they are legalized in accordance with the requirements of the countries where they are destined.
* Assist in the preparation of submissions for Health Canada (e.g. Level III Changes, Notifiable Changes, etc.) and publish submissions in eCTD format.
* Perform regulatory impact analysis as part of change controls.
* Retrieve, file and submit Adverse Drug Reports and Mandatory Problem Reports to Health Canada.
* Assist in preparation of Periodic Benefit-Risk Evaluation Reports (PBRERs).
* Perform on-going monitoring of scientific literature.
* Monitor the Health Canada, ICH and other relevant international databases for updated regulatory guidance documents. Review, analyze and interpret relevant new guidance and policy documents.
* Maintain all regulatory electronic files at BLES Biochemicals.

**Skills and qualifications include:**

* Post Graduate Certification in Regulatory Affairs
* University Degree in Life Sciences
* Knowledge of Canadian *Food and Drug Regulations* for human pharmaceuticals
* Proficient skills in MS Office Suite programs and Acrobat
* Familiarity with eCTD submissions (asset)
* The ability to work and cooperate with others to accomplish group, and corporate goals and objectives
* The ability to manage several projects at once while setting specific goals and timelines for completion
* Good analytical and problem-solving skills
* Attention to detail
* Strong time management skills
* Excellent communication skills, both written and verbal

**If interested, please submit resume and cover letter to:**

**Heather Cook, Human Resources Specialist**

**hcook@blesbiochem.com**

***BLES Biochemicals Inc. is committed to fair and accessible employment practices, including reasonable accommodation for persons with disabilities in the recruitment process and throughout employment.***