

JOIN US!

The Opportunity is Yours!

Regulatory Affairs Associate Pharmaceutical Company- London

BLES Biochemicals Inc., 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 for use in the treatment of 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, monitor submission progress and respond to correspondence in requisite timeframe.
- Obtain regulatory documents and ensure they are legalized in accordance with the requirements of the countries to which they are destined.
- Assist in the preparation of submissions for Health Canada (e.g. Notifiable Changes).
- Retrieve, file and submit Adverse Drug Reports and Mandatory Problem Reports to Health Canada.
- Assist in preparation of Periodic Safety Update Reports (PSUR).
- Monitor the Health Canada, ICH and other relevant international databases for updated regulatory guidance documents.
- Perform on-going monitoring of scientific literature.
- Maintain all regulatory electronic files at BLES Biochemicals.

If you have:

- 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 analytics and problem-solving skills
- Attention to detail
- Strong time management skills
- Excellent communication skills, both written and verbal

And are willing to roll up your sleeves and take on any challenge to help this company continue to produce a world class product, work with a great team, and receive a competitive compensation package, then we would like to talk to you.

Please reply in confidence with a cover letter to our HR Specialist, Jenny Mellor at jmellor@blesbiochem.com

BLES Biochemicals welcomes and encourages applications from people with disabilities. Accommodations are available on request for candidates taking part in all aspects of the selection process.