NoNO Inc.

Position:	**Regulatory Affairs Project Leader**
Reports to:	**Director, Regulatory Affairs**
Status:	**Permanent**

NoNO Inc. is accepting applications for the position of **Regulatory Affairs Project Leader** to be based in Toronto.
The successful candidate will provide regulatory support to the Director of Regulatory Affairs and ensure compliance with applicable US and international regulations; prepare product submission documentation, and provide guidance to project teams as it relates to the application of regulatory requirements to company activities.

RESPONSIBILITIES INCLUDE BUT ARE NOT LIMITED TO THE FOLLOWING:

- Prepare high quality regulatory documents to be submitted to the FDA and International regulatory agencies (for clinical, CMC and/or procedural) and ensure that those documents meet regulatory requirements.
- Demonstrate an ability to translate technical information into submission-ready documents.
- Assist in planning, coordinating, preparing briefing documents for regulatory agency meetings or teleconferences.
- Interpret and apply US and International regulations in order to develop regulatory strategy and content for global submissions. Communicate regulatory requirements through good verbal and written communication skills. Contact Health Authorities for routine questions under supervision.
- Manage multiple projects and work effectively across the organization to complete projects on time to meet both business and compliance needs, whether as project lead or as support role.
- Participate in project/product-related discussions and provide strategic, scientific and regulatory input in depth on clinical/labeling, CMC, advertising and promotion and/or procedural aspects.
- Participate on multidisciplinary project teams e.g., manufacture, technology transfer, etc., and make sure short and long term regulatory plans and strategies are met.
- Assist in coordinating and maintaining a document control system for pertinent regulatory documents.
- Assist in preparing departmental SOPs that are related to regulatory affairs and making sure that they are up to date.
- Work collaboratively and effectively with other company employees, consultants and subcontractors.

QUALIFICATIONS

- Bachelor's degree in life sciences or related discipline required
- At least 4+ years of industry experience in Regulatory Affairs
- Working knowledge of regulations (Canada, U.S.& International)
- Must have previous experience interacting with regulatory agencies and experience in the preparation and maintenance of new drug active substance dossiers (both investigational and marketing applications).
- Sound knowledge and understanding of eCTD format (hands on experience highly preferred)

- Good interpersonal skills, with the ability to prioritize, multi-task and work well in a team environment.
- Strong communication & project management skills
- Must be legally authorized to work in Canada without restriction.
- Minimal travel may be required
- Salary commensurate with experience
- Expertise in MS Office and Adobe Acrobat specific to regulatory publishing

Applications to:
RAjobs@nonoinc.ca
Subject: RA PL