Regulatory Affairs Specialist wanted for Aleon Pharma International, Inc. in Parsippany, New Jersey, with Master's Degree in Regulatory Affairs, Project Management, or a closely related field. Candidate must have at least one year of experience in regulatory affairs and must have knowledge of FDA regulations; Food, Drug and Cosmetic Act; IND; NDA; GMP; GLP; Filing of CTD; Drug product development process; Drug product commercialization process. Job duties to be performed:

Prepare regulatory documents for filing of CTD with FDA, including writing, publishing, correct placement in eCTD hierarchy.

Responsible for multiple IND and NDA project deliverables and timelines from clinical trials to approvals using knowledge of project management and relevant regulations including FDA regulations, GMP, GLP, and Food, Drug and Cosmetic Act.

Coordinate and support in the preparation of clear and concise responses to FDA Information Request, comments and queries.

Prepare and review FDA submission documents (drug development process, drug commercialization process, etc.), meeting packages and other submission related documents to ensure compliance with the FDA requirements and industry standards.

Communicate with regulatory agencies regarding pre-submission strategies, compliance requirements, or clarification and follow-up of submissions under review.

Track project progress using project management tools such as Asana, evaluate the project risks, and specify project plans for multiple projects/submissions for various sponsors.

Communicate cross-functionally to develop detailed project plans and timelines to successfully achieve project milestones.

Please send resume to careers@aleonpharma.com using subject line: DJB-RAS/Aleon Pharma International Inc.