



Aleon Pharma International, Inc.

*Dedicated for Approval®*

**Make Work Worth It**

[www.aleonpharma.com](http://www.aleonpharma.com)

## **Project Manager, Regulatory Affairs – Preclinical**

Are you searching for a rewarding position where you will have extraordinary and fast-track career growth opportunities working for a company that is committed to your success and provides direct training from industry experts and the knowledge you need to succeed? If so, you may be a perfect fit at Aleon!

**Job Type:** Full-time

### **Job Responsibilities:**

- Prepare and review documents for Investigational New Drug Applications (INDs), including nonclinical study reports, investigator's brochures (IBs), clinical study protocols, clinical reports, summary documents, and other regulatory documents required for submission.
- Prepare and review special applications (including Orphan Drug Designations (ODDs), Fast Track Designations (FTDs), Breakthrough Therapy Designations (BTDs), and more).
- Prepare and review development safety update reports (DSURs).
- Provide nonclinical development strategies for IND-enabling studies.
- QC regulatory documents for compliance with FDA requirements, ICH requirements, and industry standards.
- Ensure consistency of clinical documents to maintain Aleon's high-quality standards.
- Facilitate the finalization process of regulatory documents for submission.
- Manage project planning, operation, and reporting of assigned projects as needed.
- Effectively manage the communication with the sponsor and vendors as an IND project lead throughout the project.

### **Qualifications:**

- PhD/PharmD/Masters in a scientific discipline (toxicology, biological sciences, pharmaceutical sciences, etc.).
- Medical / Scientific writing experience or training preferred.
- We are willing to train exceptional candidates who can demonstrate quality and potential.

### **Skills and Requirements:**

- Organized: Follows developed company goals and plans, stays very aware of all to-dos and events.
- Can-do attitude: Dares to try new methods, dares to reach out in an unfamiliar environment.
- Innovative: Seeks to implement improvements to make their role and Aleon more efficient.
- Time Management: Capability to plan carefully and meet project timelines.
- Hard working: Works diligently and effectively.
- Collaborative: Reaches out to peers and collaborates well with other functions.

### **What We Offer to You:**

- Aleon offers competitive compensation with many benefits, including paid time off, 401(k), profit sharing, health and life insurance, and much more.
- Aleon has a dynamic and flexible working environment where professionals dedicated to learning can truly thrive.
- Limitless learning possibilities, and fantastic career advancement opportunities.
- Friendly and positive work environment.
- Dynamic company culture where employees are engaged and motivated.

We are confident that you will find that Aleon is a very rewarding and exciting place to work. If you feel that you are a good fit for this position, email your resume with confidence to [careers@aleonpharma.com](mailto:careers@aleonpharma.com).

**Inc.'s 2021 Best Workplaces Honoree.**

**Inc.'s 2020 Best Workplaces – National top 5% for employee engagement.**

**2018 Outstanding Employer Award (1 out of the 3 winners) by New Jersey Business & Industry Association.**

Aleon Pharma International, Inc. is an equal opportunity employer.

Candidate must be authorized to work in the US.