Aleon Pharma International, Inc.
Dedicated for Approval®

Make Work Worth It

www.aleonpharma.com

Senior Manager/Associate Director, Regulatory Affairs: Nonclinical

**Title is flexible based on candidate's experience.*

Are you looking for the next step in your career in the field of drug regulatory affairs? If you are passionate about expediting innovative drug development programs to meet patient needs and willing to continuously learn about health authority regulations and advanced technology, you may be a perfect fit for us. Aleon Pharma International, Inc. (Aleon) is an established full-service regulatory affairs consulting firm with operations in the US, EU, and China. This position is highly rewarding as you will have extraordinary and fast-track career growth opportunities by exploring all areas of regulatory affairs. Do not miss this chance to take your career to the next level, and **apply today by sending your resume** to careers@aleonpharma.com!

Base Salary: $130,000 - $170,000
Total Compensation: $167,500 - $217,500 (including: annual bonus, 401(k), profit sharing, and full coverage health insurance)

Job Type: Full-time
Job Location: Parsippany, NJ. Remote work is acceptable.

Job Responsibilities:

- Act as a nonclinical subject matter expert (SME) at Aleon.
- Prepare and review documents for Investigational New Drug Applications (INDs), including nonclinical study reports, investigator's brochures (IBs), clinical study protocols, M2 summary documents, and other regulatory documents required for submission.
- Prepare and review documents for NDA/BLA submissions, including M2 documents.
- Prepare and review meeting requests and meeting packages for meetings with FDA, EMA, etc.
- Review and evaluate nonclinical data and provide strategic guidance to Aleon's internal teams and clients.
- Provide expertise on GLP study design.
- Develop regulatory strategies for nonclinical toxicology and safety assessment studies.
- Conduct nonclinical gap analysis and prepare gap analysis reports for clients.

- Interpret relevant FDA guidance documents and provide updates on new industry standards and upcoming FDA and ICH requirements.

Qualifications:

- PhD in a scientific discipline (toxicology, pharmacology, biological sciences, etc.).
- At least 3 years of working experience as an FDA CDER/CBER nonclinical reviewer.

Skills and Requirements:

- Organized: Follows developed company goals and plans and 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.
- Excellent English communication, presentation and interpersonal skills.

What We Offer to You:

- Competitive compensation with many benefits, including paid time off, performance-based bonus, 401(k), profit sharing program, health, dental, vision, and life insurance, and much more.
- 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**.

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.