Aleon Pharma International, Inc.

Dedicated for Approval®

Make Work Worth It

www.aleonpharma.com

Project Manager, Regulatory Operations & Project Management

Aleon Pharma International, Inc. (Aleon), headquartered in Parsippany, New Jersey, is a consulting firm dedicated to providing global regulatory affairs, clinical development, pharmacovigilance, and quality and compliance services. For more than 14 years, our experienced team has worked closely with innovative sponsor companies and offered solutions tailored to each client's individual requirements. As a result, our clients expedite their product development and reach patients sooner to ultimately save more lives.

- Inc.'s Best Workplaces Honoree – National top 3% for employee engagement
- Inc.'s Best Workplaces – National top 5% for employee engagement
- Outstanding Employer Award by New Jersey Business & Industry Association

Job Type: Full-Time

Job Location: Parsippany, NJ (Hybrid WFH)

Job Responsibilities:

- Lead regulatory affairs projects, including formal meetings with the FDA, Investigational New Drug (IND) applications, NDAs/BLAs (New Drug Applications / Biologics License Applications), Orphan Drug Designation (ODD) applications, expedited program applications, and more from project initiation to project completion.
- Manage projects through effective communication with Aleon's clients and internal department heads and team members to successfully achieve project milestones.
- Ensure that projects are completed within the timeline, scope, and budget.
- Maintain professional relationships with Aleon's clients and strategic partners.
- Utilize Aleon's Asana project management software for streamlining project activities and accurately recording hours data.
- Review resource availability and allocation and identify areas for improving efficiency.
- Set project priorities by communicating with senior management.
- Serve as the primary liaison between the FDA and Sponsors to ensure regulatory understanding and compliance
- Analyze and summarize complex scientific and clinical data for the preparation and review of regulatory documents

Qualifications:

- Advanced degree in pharmaceutical or scientific background required.

Skills and Requirements:

- Excellent leadership, organizational, time management, and communication skills.
- Strong desire to learn.
- Ability to balance multiple projects and adapt to changes in timelines and client priorities.
- Creative and open-minded.
- Proactive and ambitious.
- Ability to set priorities by working with senior management.
- Proficiency in assessing and communicating scientific data for regulatory document preparation.

What We Offer to You:

- Aleon offers 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.
- 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**

Equal opportunity employer.

Candidate must be authorized to work in the US.