



Aleon Pharma International, Inc.

Dedicated for Approval®

Make Work Worth It

www.aleonpharma.com

Project Manager, Regulatory Operations Project Management

Aleon Pharma International headquartered in Parsippany, NJ is a global regulatory affairs consulting firm. For more than 12 years, our experienced regulatory professionals have partnered with sponsor companies at the forefront of creating and advancing innovative therapies.

- Inc.'s 2021 Best Workplaces Honoree – National top 3% for employee engagement
- Inc.'s 2020 Best Workplaces – National top 5% for employee engagement
- 2018 Outstanding Employer Award by New Jersey Business & Industry Association

Job Type: Full-Time

Job Location: Parsippany, NJ (Hybrid WFH)

Job Responsibilities:

- Manage regulatory projects (including pre-IND meetings and other formal meetings with FDA, IND preparation and submission, NDA/BLA preparation and submission, special applications, etc.) from project initiation to project completion.
- Communicate directly with FDA project managers and represent the company in formal meetings with FDA (Type A, B, C, D, etc.)
- Communicate directly with all functional teams to develop detailed project plans and timelines to successfully achieve project milestones.
- Support the preparation and review of regulatory documents to be submitted to FDA to ensure the overall quality and compliance with requirements.
- Utilize Asana project management software for streamlining the project management function activities.
- Develop/update internal guidelines/guidances including pre-IND meetings and other formal meetings with FDA, IND preparation and submission, NDA/BLA preparation and submission, special applications, etc. based on changes from FDA.

Qualifications:

- Pharm.D. or Master's degree in pharmaceutical / scientific background or Bachelor's degree with at-least 2 years of pharmaceutical / biotech industry or research experience required.
- We are willing to provide training to exceptional candidates who can demonstrate quality and potential.

Skills and Requirements:

- Excellent organization skills.
- Excellent interpersonal, written, and oral communication skills.
- Effectively lead informal/formal meetings or training sessions.
- Strong desire to learn and ability to thrive in a dynamic and fast-paced environment.
- Creative and open-minded.
- Proactive and ambitious.
- Passionate desire to learn.
- Excellent time management.
- Outstanding leadership skills.
- Excellent collaboration.
- Ability to set priorities by working with senior management.
- Proficiency in Microsoft Office Suite (especially in Word and Excel).

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.