Pfizer Inc.

Sr. Associate Regulatory Affairs - Combination Product

Why Patients Need You

We're looking to bring medicines to the world faster and we are not willing to compromise on excellence and integrity. Adhering to local and global regulations is essential and the ever-changing regulatory environment requires forward thinking and attention to detail. Your dedication and expertise will help expand and accelerate patient access to Pfizer medicines and vaccines.

What You Will Achieve

You will represent Pfizer as an approval liaison in the regulatory affairs team. You will play the critical role of providing strategic product direction to teams while interacting with regulatory agencies and negotiating with them to expedite approval of pending registrations. Due to your expertise, you will be the regulatory liaison on the project team throughout the product lifecycle and a regulatory representative to marketing or research project teams and government regulatory agencies. Your understanding of regulatory procedures will help in development of submission of product registration, progress reports, supplements, amendments and periodic experience reports.

As a Senior Associate, your knowledge and skills will contribute towards the goals and objectives of the team. Your focus and ability to meet team targets will help in completing critical deliverables. Your innovative use of communication tools and techniques will facilitate in explaining difficult issues and establishing consensus between teams.

It is your dedication and focus that will help in making Pfizer ready to achieve new milestones and help patients across the globe.

Breakthroughs that change patients' lives... At Pfizer we are a patient centric company, guided by our four values: courage, joy, equity and excellence. Our breakthrough culture lends itself to our dedication to transforming millions of lives. We value every employee and throughout their career encourage them to grow, develop and express their views freely.

How You Will Achieve It

- Contribute to the completion of complex projects, manage own time to meet agreed targets and develop plans for work activities on own projects within a team.
- Assist in developing and implementing regulatory strategy that aligns with business needs, including growth projects and activities relating to maintaining registrations, product defense and regulatory compliance.
- Execute, through use of standards and tools, designated operational tasks or through the applicable Pfizer country office, conforming to regulatory submission milestones and applicable regulatory obligations.

Qualifications

Must-Have

- Bachelor's Degree
- 3+ years of demonstrated experience in regulatory affairs or in a regulated industry.
- **Medical Device Regulatory Affairs experience required.**
- Knowledge of the regulatory environment and how this impacts regulatory strategy development and implementation.
- Proven ability to consistently deliver to time, cost and quality standards.
- Strong problem solving skills and team orientation.
- Excellent written and verbal communication skills.
- Good knowledge of Windows and Microsoft Office.

Nice-to-Have

- Master's degree
- Relevant regulatory experience.
- Awareness of and ideally experience in successfully communicating with Health Authorities.
- Familiarity with medical device/pharmaceutical organizational structures, systems, and culture.

Other Job Details:

- **Last Date to Apply for Job: March 23, 2021**
- **Additional Locations:** USA - Remote
- Eligible for Employee Referral Bonus

INTERESTED CANDIDATES PLEASE APPLY AT:

https://pfizer.wd1.myworkdayjobs.com/PfizerCareers/job/United-States---Illinois---Lake-Forest/Sr-Associate-Regulatory-Affairs---Combination-Product_4806122