Pfizer Inc.

Manager - Regulatory Affairs - Device and Combination Products

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, and amendments.

As a Manager, you provide guidance to operational teams for managing projects. Your planning skills will help in preparing forecasts for resource requirements, and providing areas of improvement for products, processes or services. Through your comprehensive knowledge of principles, concepts and theories of the discipline, you will also work towards advancing new concepts and methodologies. You will be able to take a leadership role to facilitate agreements between different teams.

It is your dedication 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

- Provide guidance, lead/co-lead projects, manage own time to meet objectives, and plan resource requirements for projects across the division.
- Liaise with and provide input/direction to Global Chemistry Manufacturing and Controls, and any other key stakeholder to ensure the filing strategies for initial registrations and the lifecycle submissions are defined and executed and the regulatory requirements are met, ensuring a submission ready dossier.
- Work in collaboration across the organization with stakeholders to deliver efficiencies in regulatory submissions and processes.

Qualifications

Must-Have

- Bachelor's Degree
- 5+ years of demonstrated experience in regulatory affairs or in a regulated industry.
- **Medical Device Regulatory Affairs experience required.**
- Demonstrable experience of effective delivery in a complex matrix environment.
- Regulatory experience including knowledge of New Drug Application (NDA)/Investigational New Drug (IND)/510(k)/PMA submission processes.
- In depth knowledge of national/regional regulatory legislation and guidelines.

- Knowledge of pharmaceutical analytics technology, pharmacology, toxicology and medicine.
- Leadership qualities and management skills, team oriented with problem solving skills.
- Strong written and verbal communication and interpersonal skills.

Nice-to-Have

- Master's degree
- Relevant pharmaceutical experience.

Other Job Details:

- **Last Date to Apply for Job: March 22, 2021**
- **Additional Locations:** USA - Remote
- Eligible for Relocation Package: YES
- Eligible for Employee Referral Bonus: YES

INTERESTED CANDIDATES PLEASE APPLY AT:

https://pfizer.wd1.myworkdayjobs.com/PfizerCareers/job/United-States---Illinois---Lake-Forest/Manager---Regulatory-Affairs---Device-and-Combination-Products_4806152