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## Director, Global Regulatory Lead

2310733

A career at Pfizer offers opportunity, ownership and impact. All over the world, Pfizer colleagues work together to positively impact health for everyone, everywhere. Our colleagues have the opportunity to grow and develop a career that offers both individual and company success; be part of an ownership culture that values diversity and where all colleagues are energized and engaged; and the ability to impact the health and lives of millions of people. Pfizer, a global leader in the biopharmaceutical industry, is continuously seeking top talent who are inspired by our purpose to innovate to bring therapies to patients that significantly improve their lives.

### Responsibilities

- Provide strategic regulatory expertise as Global regulatory representative to Product/Project Team(s).
- Lead and coordinate a virtual global regulatory strategy team (GRST), encompassing in country regulatory colleagues from North America, EMEA, APAC & LATAM as appropriate.
- Through the GRST, develop, align, manage and implement the global regulatory strategy and risk assessment including determination of regulatory probability of success and risk mitigations.

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## Details

**Posted:**  
October 4, 2017

- Be accountable for delivering the project goals and aligning the regulatory strategy with global and business regional needs.
- Be accountable for timely submissions and approvals with commercially attractive labelling across the regions.
- Be accountable for development of core dossiers for new multi-region projects.
- Help ensure optimal regulatory interactions with Health Authorities in relation to the assigned project(s).
- Project(s) assigned can be in development and/or at post-authorization stage.
- Role may have direct reports
- Responsible for the production, updating and communication of global regulatory strategies, and regulatory probability of success for assigned projects/products.
- Provides regulatory expertise and leadership for the project/product.
- Member of appropriate Project(s)/Product(s) teams.
- In partnership with the Project/Product Team Leader accountable for the delivery of the Project/product goals according to the endorsed Global Regulatory Strategy.
- Ensures appropriate representation for Pfizer for the project/product with Health Authorities.
- Ensures rapid reporting and dissemination of regulatory agency contact information and project/product communications to appropriate team and colleagues
- Ensures that all regulatory development process commitments are clearly communicated, monitored and met.
- Mentoring, developing regulatory professionals who are assisting in meeting the project/product objectives.

**Location:**

New York

**Salary:**

Open

**Type:**

Full Time - Experienced

**Categories:**

Quality/Risk Management, Regulatory Compliance

**Preferred Education:**

Doctorate

**Qualifications**

- BS/BA is required. MS, PharmD, PhD or MD preferred. Equivalent workplace experience can be considered.

- Advanced knowledge of regulations across more than one region preferable.
- Working knowledge of other regulations and their associated challenges for global development programs.
- Extensive direct regulatory experience, preferably including as a Global Regulatory Lead and leading a GRST.
- Direct experience with development & management of regulatory submissions for a major country and/or region(s).
- Direct experience in communicating with major regulatory agency (ies) (i.e. FDA, EMA, CFDA, Japan), as well as participating in/leading interactions such as End-of-Phase 2, pre-submission and scientific advice meeting(s).
- Understanding of clinical trial design and management.
- Understanding of GXP practices, including regulatory documentation quality processes.
- Experience working in a highly matrixed, global and multi-site environment.
- Track record of having supported at least one project of high complexity and provided strategic direction.
- Experience within different product category areas and at different stages of products life cycle.

### **NON-STANDARD WORK SCHEDULE, TRAVEL OR ENVIRONMENT REQUIREMENTS**

Primarily office based role. Some global travel required.

Pfizer is committed to equal opportunity in the terms and conditions of employment for all employees and job applicants without regard to race, color, religion, sex, sexual orientation, age, gender identity or gender expression, national origin, disability or veteran status. Pfizer also complies with all applicable national, state and local laws governing nondiscrimination in employment as well as work authorization and employment eligibility verification requirements of the Immigration and Nationality Act and IRCA. Pfizer is an E-Verify employer.

- **Last Date to Apply for Job: October 12, 2017**
- **Grade: 17**

- **Eligible for Employee Referral Bonus:Yes**

### **EEO & Employment Eligibility**

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### **Sunshine Act**

Pfizer reports payments and other transfers of value to health care providers as required by federal and state transparency laws and implementing regulations. These laws and regulations require Pfizer to provide government agencies with information such as a health care provider's name, address and the type of payments or other value received, generally for public disclosure. Subject to further legal review and statutory or regulatory clarification, which Pfizer intends to pursue, reimbursement of recruiting expenses for licensed physicians may constitute a reportable transfer of value under the federal transparency law commonly known as the Sunshine Act. Therefore, if you are a licensed physician who incurs recruiting expenses as a result of interviewing with Pfizer that we pay or reimburse, your name, address and the amount of payments made currently will be reported to the government. If you have questions regarding this matter, please do not hesitate to contact your Talent Acquisition representative.

Interested Candidates please apply at:

[https://pfizer.wd1.myworkdayjobs.com/PfizerCareers/job/USA--NJ---Madison/Director--Global-Regulatory-Lead\\_1054488-1](https://pfizer.wd1.myworkdayjobs.com/PfizerCareers/job/USA--NJ---Madison/Director--Global-Regulatory-Lead_1054488-1)

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## About 2310733

Pfizer Global Research and Development (PGRD), Pfizer's discovery and development division, is one of the finest pharmaceutical research institutions in the world. Our focus is clear - to discover and deliver an ever-increasing variety of medicines to significantly enhance the health and quality of life for people and animals around the world. We accomplish this with multidisciplinary teams of sci...

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