



**Senior Regulatory Affairs Manager
Rockaway, NJ**

The Senior Regulatory Affairs Manager, working closely with a Director/Senior Director, will focus on US Regulatory requirements and represent the regulatory affairs function on one or more project teams supporting development and/or marketed product activities. The Senior Regulatory Affairs Manager will serve as the primary point of contact with FDA for assigned projects/products. Within the regulatory function, the Senior Regulatory Affairs Manager will collaborate closely with other regulatory functions including Regulatory-Operations, Regulatory-CMC, Regulatory-Advertising & Promotion, and Regulatory Program Management-EU/Rest of World to ensure business needs are met.

About Warner Chilcott

Warner Chilcott is a leading specialty pharmaceutical company currently focused on the women's healthcare, gastroenterology, dermatology and urology segments of the U.S. and Western European pharmaceuticals market. It is a fully integrated company with internal resources dedicated to the development, manufacturing and promotion of its products. We have established strong franchises in women's healthcare and dermatology through our marketing techniques and specialty sales forces. We believe that our proven product development capabilities, coupled with our ability to execute acquisitions and inlicensing transactions and develop partnerships will enable us to sustain and grow our business.

The individual will be responsible for the following activities:

- Provides US regulatory strategy and tactical support to cross-functional development and product teams.
- Coordinate and lead cross-functional groups for regulatory activities and deliverables ensuring applicable requirements & regulations are met.
- Author and/or compile regulatory documentation to be submitted to FDA to support ongoing activities pre-IND through phase IV, including, but not limited to, annual reports, meeting requests and associated briefing packages, protocol amendments, new drug applications, etc.
- Serve as the primary contact for FDA on assigned projects.
- Oversee additional regulatory projects as assigned

Qualifications:

- Bachelors degree plus 3+ years relevant regulatory affairs and/or drug development experience
- Basic working knowledge of core drug development and registration processes

- Job knowledge – possesses working knowledge of US regulations, regulatory environment, general drug development and scientific/therapeutic areas of interest
- Leadership – provides strategic direction, sets goals/milestones and independently monitors progress, can delegate responsibility
- Communication skills – very strong written and verbal communication skills, ability to be effective not only in small 1-on-1 settings but in larger group settings, can communicate effectively with colleagues at various sites around the world
- Interpersonal skills – able to work well within cross-functional teams, fostering a positive and collaborative culture and unifying team dynamics
- Critical thinking skills – ability to independently analyze problems and develop potential solutions outlining associated pros and cons; can articulate and discuss complex issues appropriately with varying audiences

Candidates must be authorized to be employed in the United States. Candidates should be willing and able to travel as necessary. Candidates must be organized and have excellent oral presentation and communication skills. Candidates must also successfully pass a drug test and background check.

Warner Chilcott realizes that our success as an organization is dependant upon our people. We seek aggressive, success oriented and adaptable associates. Please apply at jobs@wcrx.com and reference “SrMgrReg” in the subject.