LEO Pharma Inc.

Title: Intern, Regulatory Affairs

Location: Parsippany, NJ

Job Type: Summer Co-op/Internship

Compensation Type: Hourly    Wage: $15.00

Start Date: 6/6/2016     End Date: 8/5/2016

Job Description: We currently have an opening for an Intern, Regulatory Affairs in our Parsippany, NJ headquarters. You will be responsible for focusing your efforts on gaining practical experience within our Regulatory Affairs group as well as applying your knowledge, skills, and abilities to improve a process identified within this department. This individual will be engaged in a 9 week commitment that encompasses meaningful work coupled with a presentation at the end of the program.

Primary Responsibilities:

- Acquire hands-on knowledge of the structure and content of an Investigational New Drug Application (IND) and an approved New Drug Application (NDA) and all subsequent amendments and supplements.
- Work with a LEO team member to plan, organize, and carry out the annual Regulatory Affairs Team Building Event. Interact with third party vendors and LEO staff to negotiate terms, schedule, and coordinate a large group function.
- Provide assistance with the review of other Regulatory documentation. This will include project management and compilation of Annual Reports (AR), Periodic Ad-verse Drug Experience Reports (PADERS), and other routine regulatory filings, including associated cover letters and forms. Other documents may include labeling components beyond the USPI (US Prescribing Information), scientific reports, responses submitted in reply to FDA comments or questions, etc.
- Working with another Regulatory Affairs team member, perform a CCDS (Company Core Data Sheet)/USPI (US Prescribing Information) comparison for Enstilar® to harmonize these data sheets and, if needed, help to develop documentation to be presented to the Labeling Committee in Denmark.

Qualifications: A current student or recent graduate majoring in one of the sciences seeking to explore opportunities within Regulatory Affairs and the pharmaceutical industry. This individual will be passionate about helping patients, eager to learn, bring a fresh perspective to the way we work, and can work 37.5 hours per week.

Application Instructions: Please forward all resumes to adam.willard@leo-pharma.com
About the Organization:

LEO Pharma is an independent, research-based specialty pharmaceutical company committed to the discovery and development of novel drugs for patients within the area of dermatology in the U.S. For 105 years our products, which are marketed in more than 100 countries worldwide, have improved the quality of millions of people's lives around the world.

We understand that people power our success. Our global team – consisting of around 4,800 people in 61 countries worldwide – is LEO Pharma’s greatest asset. Thanks to this incredible mix of people from different cultures and backgrounds, LEO Pharma is a workplace where innovation thrives and people grow.

This is why we continually seek to attract passionate, dedicated and solution-orientated people and ensure that our people develop professionally. Our future depends on people who can drive our activities, penetrate new territories, realize potential in existing markets and build an even stronger pipeline. If LEO Pharma is to realize its vision, we need people who think innovatively and act with integrity.

Disclaimer Information: Equal Opportunity Employer