RAFAEL Pharmaceuticals, Inc.
"To Save A Life Is To Save A Universe"

1 Duncan Drive
Cranbury, New Jersey 08512
Tel: (609) 409-7050
Fax: (609) 409-6035

Date: July 12, 2019

Position: Director of Pharmacovigilance

Job Description

OBJECTIVES:

The Director of Pharmacovigilance will directly manage and oversee the Rafael's drug safety and pharmacovigilance process including the detection and analysis of safety issues for investigational drug products in compliance with global pharmacovigilance and regulatory requirements.

Key Responsibilities:

- Ensure that all global pharmacovigilance obligations are fulfilled and that all the required PV activities are in line to support assigned clinical trials and to ensure subject safety
- Maintain pharmacovigilance expertise, and understanding of international safety regulations and guidelines, and global HA/ethics expedited and periodic submission requirements
- Prepare or review Safety Management Plans (SMPs), Reconciliation Plans and other safety-specific plans in liaison with clinical development teams and CROs
- Oversee clinical assessment of adverse events, SAEs, SUSARs and safety signals collected from clinical trials, and post-marketing surveillance in the assigned therapeutic indications
- Overall responsibility for assessing expectedness and company causality in a timely manner
- Medical follow-up of clinical trial cases with the CROs for missing/clarification of safety information in a timely manner
- Provide proactive risk assessment
- Responsible for signal detection and evaluation
- Identify and implement proactive safety analysis strategies to further define the safety profile of a product
- Lead aggregate safety data review activities and coordinate safety surveillance activities
- Provide Safety input/review of clinical study protocols, clinical study reports, Investigator Brochures, and case report forms for bioequivalence, bioavailability and safety/efficacy studies
- Provide support for planned INDs/NDAs including drafting and editing of safety modules for submission
- Ensure generation, consistency, and quality of safety sections in submission documents.
- Author responses to health authorities' questions

EDUCATION, BEHAVIOURAL COMPETENCIES AND SKILLS:

- M.D. or PharmD
- Minimum 5 years of global pharmacovigilance experience
- Drug safety experience in a global pharmaceutical or global CRO is preferred
- Must possess a strong clinical and scientific background. Must be familiar with electronic safety databases and coding dictionaries

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- Must possess knowledge of international pharmacovigilance regulations and drug development processes
- Able to develop and document sound risk assessment
- Able to work collaboratively within the organization
- Demonstrates leadership within cross-functional team environment for safety related issues
- Good communication skills (verbal and written).
- Ability to solve problems with a variety of complex variables through non-standardized solutions that require independent judgement and analysis
- Ability to write scientific reports and technical correspondence
- Must possess computer skills by using MS Word, Excel, and Microsoft Outlook
- Ability to read and interpret comprehensive and intricate research documents
- Proficiency in speaking, comprehending, reading and writing in English is required.
- Ability to undertake periodic domestic and infrequent international travel (to sites or to Investigator or CRO meetings

ABOUT RAFAEL PHARMACEUTICALS:

Rafael Pharmaceuticals, Inc. is a privately held, clinical stage, oncology-focused pharmaceutical company, established in 2002. It is committed to the development and commercialization of therapies that exploit the metabolic differences between normal and cancer cells. Company's flagship molecule CPI-613® (devimistat) is developed in 'Altered Energy Metabolism-Directed (AEMD)' platform. CPI-613® (devimistat) is in late stage of clinical development for multiple hematological malignancies and solid tumors. It has shown excellent safety and promising efficacy profile as a single agent, as well as in combination with standard therapy in Phase II clinical trials in relapsed or refractory patient population. Rafael also has an outstanding leadership team highly experienced in oncology development and commercialization. Several team members were associated with successful development and global launch of oncology products in the past.

Rafael is committed to equal employment opportunity and non-discrimination for all employees and qualified applicants without regard to a person's race, color, sex, gender identity or expression, age, religion, national origin, ancestry, ethnicity, disability, veteran status, genetic information, sexual orientation, marital status, or any characteristic protected under applicable law. Rafael is an E-Verify Employer in the United States. Rafael will make reasonable accommodations for qualified individuals with known disabilities, in accordance with applicable law. Any applicant requiring an accommodation in connection with the hiring process and/or to perform the essential functions of the position for which the applicant has applied should make a request to the recruiter or hiring manager, or contact Talent Acquisition at Rafael Pharmaceuticals.