1 Duncan Drive
Cranbury, NJ 08512 USA
Telephone: (609) 409-7050
Facsimile: (609) 409-6035

Director Regulatory Affairs

Cranbury/Newark, NJ, US

Worker Category: Active - Regular full-time

Now is an exciting time to join Rafael Pharma, a leading late stage Oncology company. Our focus is the patient "One Patient At A Time".

We are a company united by strong values – passion, customer focus, innovation, adaptability and integrity. Our values reflect the way we strive to improve the quality of life for patients, and are at the heart of our company's success and future growth.

We continue to seek passionate, dedicated, and solutions-oriented people – and consistently ensure that our people develop their talent. If Rafael Pharma is to realize its vision, we need people who think innovatively and act with integrity.

We currently have and opening for, Director Regulatory Affairs in our Cranbury/Newark NJ office.

In addition to developing its lead Cancer Metabolic molecule CPI 613 Rafael is looking to increase its breadth through co-development, partnering and acquisitions. The Director Regulatory Affairs in Rafael will be responsible or formulating the regulatory strategies for assigned development projects. Lead the implementation of regulatory strategy and programs within the project teams for assigned products. The position will report to the CEO.

RAFAEL Pharmaceuticals, Inc.

1 Duncan Drive
Cranbury, NJ 08512 USA
Telephone: (609) 409-7050
Facsimile: (609) 409-6035

Role and Responsibilities:

- Effectively oversee the preparation of regulatory submission documents in adherence with applicable Regulations and Directives for submission to government agencies

- Facilitate submission approvals and amendments through leading communications and negotiations with client, government agencies, and project team. Building positive working relationships with clients and government agency contacts

- Review and/or create study reports, clinical protocols, safety and efficacy reports for accuracy and compliance to regulations. Review of draft submissions for regulatory content and the editorial viewpoint

- Responsible for managing project workflow including prioritizing project objectives, and establishing timeframes for projects with clients. Responsible for overseeing progress and completion of projects with project team members, ensuring timeframes and deadlines are met

- Lead and participate in formal interactions (face-to-face meetings, teleconferences, etc.) with clients and government agencies. Build positive working relationships with clients and government agency contacts

- Interact with potential clients to develop new business and create win-win agreements

- Identify project issues and develop alternate strategies for presentation to client. Provide clients with strategic advice in response to their queries, based on regulatory experience and area of expertise

- Participate in or conduct quote preparation and new project / client consultations

RAFAEL Pharmaceuticals, Inc.

1 Duncan Drive
Cranbury, NJ 08512 USA
Telephone: (609) 409-7050
Facsimile: (609) 409-6035

- Build and maintain a cooperative and respectful working environment. Be available as an internal resource for peers, advising on regulatory issues and strategies

- Present industry related training seminars or workshops at industry conferences

- Participate in the planning and execution of the strategic direction for the US business

- In collaboration with key stakeholders, formulate regulatory strategies that provide a streamlined development programs while accurately interpreting and reflecting regulatory and corporate guidelines

- Plan and manage integration of multidisciplinary regulatory programs into the project team development plans for all assigned projects

- Lead the planning and conduct of meetings with regulatory agencies as appropriate

- Ensure that all documents to be submitted to regulatory agencies have been evaluated to assure that they are complete, well organized, scientifically accurate, of high quality, are in regulatory compliance, and are presented in a way that facilitates agency review

Required Skills:

- Advanced degree (M.Sc., Ph.D., M.D., Pharm.D.) in the Biological, Medical, Chemical or Engineering. BSc required

- Significant experience of pharmaceutical / biologics development in the regulatory environment, including leadership and/or senior consulting experience

- 15+ years of experience in the Pharmaceutical industry. 8+ years of experience in Regulatory strategy

1 Duncan Drive
Cranbury, NJ 08512 USA
Telephone: (609) 409-7050
Facsimile: (609) 409-6035

- Expert knowledge and understanding of the development process for pharmaceutical and Biological products including: CMC, non-Clinical and Clinical

- Working knowledge of venture capital and credit markets and their role in drug development

- Displays full knowledge of protocol, regulatory requirements, and company SOPs. Identifies, documents, and discusses protocol violations, regulatory non-compliance, and issues involving subject safety

- Must have prior experience working with FDA or EMA

- Experience of successful NDA, BLA or MAA is filing essential

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 is developed in 'Altered Energy Metabolism-Directed (AEMD)' platform. CPI-613 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.