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

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Position: Director / Senior Director, Pre-clinical Development

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**Job Description**

Rafael Pharmaceuticals is seeking a Director/Senior Director for Pre-clinical Development at our Cranbury R&D facility. The candidate will be responsible to lead development, execution, design, interpretation and presentation of GLP and Non-GLP Tox (toxicology), PK (pharmacokinetics) / PD (pharmacodynamics), ADME (absorption, distribution, metabolism, excretion), and pharmacology in vivo and in vitro studies to support pipeline. The candidate will be familiar with international regulatory guidelines and have experience with development strategies for small molecules in oncology to support rapidly growing portfolios for pre-clinical development and IND application. The candidate will be passionate and self-motivated with previous experience working and/or leading a highly collaborative cross-functional environment. This position will directly report to Chief Development Officer (CDO).

**OBJECTIVES:**

- Creatively think and build pipeline with solid and efficient pre-clinical development strategies.
- Address and resolve scientific issues arising in pre-clinical development programs and bridge between pre-clinical and clinical development.
- Serve as a subject expert in Pre-clinical development across Tox, PK/PD, ADME and pharmacology. Deeply understand drug candidates' profiles from these perspectives, provide insights into strategies and studies, and efficiently apply science/technology into projects.
- Very familiar with FDA, EMA, ICH and GLP guidelines to guarantee compliance of requirements from healthy authorities for pre-clinical development programs.
- Well align between Rafael and CROs for pre-clinical development studies, including design, protocol, execution, timeline, quality, progress monitoring, data analysis / interpretation, reports review.
- Support regulatory submission (eCTD for IND and NDA), briefing books (BB), response documents for health authority interactions and address questions/requests, as well as annual update (e.g. IB).

**EDUCATION, BEHAVIOURAL COMPETENCIES AND SKILLS:**

- Ph.D. in Toxicology, Pharmacology, DMPK or related scientific discipline. DABT is preferred.
- 10 ~ 15 years of pharmaceutical and/or biotech industry experience.
- Oncology and small molecule experience are must; cancer metabolism is a big plus.
- Extensive experience in strategic planning, program design, project and budget management.
- Solid expertise in Tox / TK, PK/PD, M&S (modeling and simulation), ADME, pharmacology, and allometric scaling from animals to human.
- Hands-on experience in managing and working with CROs.
- Strong leadership, management, communication, negotiation and presentation skills with team-playing spirit and team-building skillsets.
- Strong passion to be part of a highly innovative company aiming to save the lives of patients and help their families.

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**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.*