1 Duncan Drive
Cranbury, NJ 08512 USA
Telephone: (609) 409-7050
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Head of Manufacturing (Chemistry, Manufacturing and Controls (CMC))
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, Head of Manufacturing (Chemistry, Manufacturing and Controls (CMC)) 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 Head of Manufacturing (Chemistry, Manufacturing and Controls (CMC)) in Rafael will be responsible for company’s activities for its ongoing early- and late-stage clinical trials. The successful candidate will be responsible for evaluation, selection and technical qualification of vendors, vendor management regarding production of clinical trial materials and future commercial products, overseeing studies required for high-quality regulatory submissions, and technical review of production documents. Strategic and tactical responsibility for implementing manufacturing strategy and strategic operational goals to exceed customer expectations for product quality, cost

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and delivery, maximising efficiency, optimising production levels and driving operational excellence. Work closely with internal and external key stakeholders, regarding technical support for activities, striving for best in class products and business practices to deliver to the customer's expectations, managing teams and projects across the business. The position will report to the CEO.

Role and Responsibilities:

- Manage the supply of clinical and future commercial products in compliance with current Good Manufacturing Practices
- Ensure and maintain uninterrupted supply of clinical trial materials for all ongoing studies
- Communicate effectively to stakeholders
- Represent the CMC Team when communicating externally
- Create and maintain detailed CMC project plans to ensure clarity of deliverables and timing
- Provide support to Management in assessing resource needs to achieve timelines and quality milestones
- Develop tools and mechanisms for monitoring progress and problem solving with CMC project and functional area managers
- Manage day-to-day activities of external contractors carrying out cGMP activities

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- Provide technical and management input into evaluation, selection and qualification of contract manufacturers and associated vendors

- Work with Quality Assurance to develop and use appropriate SOPs for vendor oversight, including external change control, deviations, investigations, and data review

- Provide technical support for Batch Record approval, review, and final release of product

- Ensure timely supply of API and Raw Material in support of Drug Product production

- Prepare and review applicable CMC sections for regulatory submissions

- Overall responsibility for Manufacturing activities

- Create and implement best practice manufacturing vision, strategy, policies, processes and procedures

- Ensure that manufacturing strategies and processes are in place to meet business objectives and operational needs in terms of price, quality and delivery targets

- Contribute to overall business strategy and annual budget process

- Take ownership of the manufacturing policy, guidelines and any associated documents

- Initiate and develop creative and innovative manufacturing processes

Required Skills:

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- 10+ years of experience in a pharmaceutical or biotechnology environment managing projects in CMC areas

- Minimum BS, MS, or equivalent in biology, chemistry, bioengineering, or related field

- Experience with managing contract manufacturers and associated vendors

- Strong working knowledge of cGMPs and other requirements for pharmaceutical production

- Demonstrated understanding of the combination medical device / drug product development process from research through a commercial product including an understanding of the interdependencies of functional groups

- Proficient in relevant software: MS Project, Excel, PowerPoint, Word, etc. in addition to general knowledge with shared work environments

- Experience in GMP production, process development, scale-up engineering, analytical method development, formulation, and characterization

- Exceptional skills at facilitating teams and building consensus with membership comprised of diverse levels and areas of the company

- Demonstrable experience of leading a manufacturing function with a proven track record in strategic manufacturing leadership delivering effective manufacturing strategies, policies, processes and systems

- Proven project management and build quality experience

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- Knowledge and technical understanding of automotive processes, components and manufacturing techniques

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.