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

1 Duncan Drive
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Tel: (609) 409-7050
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Date: May 3, 2019

Position: CMC Manufacturing Lead Job Description
Report To: VP, Manufacturing & CMC RA

Job Description

OBJECTIVES:

The CMC Lead is responsible for supporting small molecule oncology drug substance and drug product manufacturing.

- This position is for a high level, experienced technical operations professional to serve as a subject matter expert and point of contact for Rafael oncology product manufacturing (for synthetic APIs in a 100% outsourced model). The candidate must have deep and broad expertise in drug substance, drug product small molecule manufacturing, analytical methods and manufacturing process development. The candidate will leverage their direct manufacturing experience to ensure the phase appropriate development are in place and fit-for-purpose to properly support all aspects of drug development and manufacture.
- This is an individual contributor role in which the candidate provides drug substance/drug product, process and analytical expertise, associated regulatory support, and manage the manufacturing aspects of the projects. This requires significant internal collaboration as well as the management of manufacturing activities conducted at external Contract Development & Manufacturing Organizations (CDMOs).

ACCOUNTABILITIES:

Drug Substance/Drug Product Subject Matter Expert

- Provide technical guidance for troubleshooting / investigating complex issues regarding the manufacturing process.
- Apply statistical analysis for interpretation of manufacturing data.
- Quickly and effectively resolve complex technical issues and deviations / investigations.
- Effectively communicate complex technical issues and deliver concise presentations to management and non-technical stakeholders.
- Provide technical input for selecting external contractors and manage day-to-day contractor activities for respective projects.
- Create and enhance collaborative and trusting relationships internally and with personnel at Contract Research Organizations (CROs).
- Support analytical development and method validation for product testing
- Serve as a peer-leader to motivate / inspire colleagues and to mentor others in various aspects of analytical and problem-solving methodologies.
- Maintain a high level of professional and technical expertise through familiarity with scientific literature, conference attendance, and participation in training courses.
- Manage the drug substance manufacturing for registration, validation and commercial launch including the appropriate documents and regulatory updates.
- Leads the interaction with contract manufacturers to ensure successful technical transfers and is considered the subject matter expert during troubleshooting activities.

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- Authors/reviews quality documentation, such as protocols, validation reports, methods, technology transfer reports, and scientific investigation reports, as well as technical reports needed to support regulatory filings.
- Apply knowledge and direct experience managing the life-cycle of the development and commercial projects.
- Apply QbD approach to define the design space as appropriate.

Regulatory Submissions

- Author and/or review relevant drug substance and drug product CMC sections for global regulatory submissions (IND/CTA and NDA/MAA and annual reports) and ensure sections meet submission ready standards regarding content and format.
- Assist with responses to regulatory agencies regarding any pre- and post-approval changes.
- Maintain awareness of current trends regarding global regulatory CMC requirements through literature and conference attendance.

Documentation/Compliance

- Ensure process knowledge documents, development reports, and specifications are compliant with internal procedures and regulatory requirements.
- Assist in the development and implementation of departmental processes, procedures and policies.
- Maintain adherence to departmental and quality systems, such as SOP training records, deviations/investigations, CAPAs, and Change Controls.
- Actively contribute to the preparation and coordination of internal audits and regulatory inspections.
- Supervise / coach less experienced staff as needed.

EDUCATION, BEHAVIOURAL COMPETENCIES AND SKILLS:

- Requires a BA/BS in chemistry, chemical engineering or other scientific discipline with 7-10 years of experience, an MS with 5+ years of experience
- Direct experience with the pilot/commercial plant manufacturing of synthetic drug substance and drug products
- Strong knowledge of ICH and other regulatory guidelines
- Knowledge and experience with phase appropriate product development and clinical supplies processes
- Experience in authoring CMC sections of IND/IMPD and NDA/MAA regulatory submissions
- Experience working with Contract Research Laboratories
- Proven experience with various quality systems (e.g. investigations / deviations, CAPAs, change controls, etc.)
- The following items are preferred:
- Knowledge and experience with statistical applications for data evaluation
- Knowledge of European, Japan and US CMC regulatory requirements for drug substance and drug products
- Familiarity with MHRA / FDA inspections and compliance experience

LICENSES/CERTIFICATIONS:

- PMP Certification is a plus
- RAC Certification is a plus

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TRAVEL REQUIREMENTS:

- Ability to travel to various meetings or client sites, including overnight trips. Mostly domestic, but some international travel may be required.
- Position requires up to 15% domestic and international travel.