Senior Director, Regulatory Affairs  
Eureka Therapeutics, Inc.

Location: Emeryville, CA  
Position type: Full-time

About Eureka Therapeutics, Inc:

Eureka Therapeutics is a privately-held biotechnology company focused on developing novel T cell-based immunotherapies for hematological malignancies and solid tumors. Our unique platform is powered by TCR-like antibodies, which recognize previously inaccessible cancer antigens specific for solid tumors. We have built strong pipelines of innovative drugs, with the most advanced candidates in clinical stage. In addition to our internal drug discovery programs, Eureka has ongoing partnerships with Memorial Sloan Kettering Cancer Center, City of Hope National Medical Center, and Boehringer Ingelheim. To learn more about us, please visit our website at www.eurekatherapeutics.com.

Job Description:

The Senior Director, Regulatory Affairs will be reporting directly to the Chief Medical Officer (CMO) and will be responsible for implementation of all regulatory activities within the organization.

Responsibilities include, but are not limited to:

- Responsible for the coordination, preparation, review and timely filing and maintenance of regulatory submissions (INDs, DMFs, CTAs, amendments, safety reports, annual updates, briefing documents, orphan drug applications, pre-meeting packages, post-approval submissions and marketing applications to the FDA, and if required international regulatory authorities). Ensures appropriate follow-up correspondence, such as re-submissions.
- Along with the CMO, serves as interface with reviewers from FDA and other health authorities. Coordinates activities for meetings with FDA and other regulatory authorities.
- Leads the hands-on preparation and coordination in preparation and authorship of regulatory documents in clinical programs, Chemistry, Manufacturing, and Controls (CMC) quality, process improvement, and laboratory quality.
- Interprets and communicates regulatory expectations to internal and external stakeholders (including partners, CROs, CMOs, consultants, and contractors) in order to execute program objectives in compliance with applicable regulations. Coordinates with cross-functional teams to define contributions to submissions.
- Maintains current knowledge of regulations and guidelines (FDA, ICH, and others as required). Ensures compliance with health authority regulations. Oversees implementation of regulatory strategy and activities needed to secure approval of new drugs.
- Reviews clinical study protocols, clinical study reports, investigator brochures, and CMC reports.
- Interprets pre-clinical and clinical results and develop those into sound regulatory positions and strategy.
- Develops and maintains cooperative relationships with external vendors and regulatory health authorities.
- Interfaces with international affiliates on regional regulatory strategy and implementation plans.
- Ensures that budgets and schedules meet corporate timelines.
- Other duties as assigned.

Position Requirements & Experience:

Overall Background
- >12 years of experience or equivalent of regulatory drug development including product approval/launch, with >8 years in leadership position.
- Advanced degree in a science related field (PhD, PharmD etc.).
Regulatory Competencies
- Demonstrated experience in preparing new IND/CTA and/or marketing application submissions.
- Demonstrated success in submission and approval of BLAs.
- Demonstrated knowledge of regulatory aspects of biologics/ gene/ cell/ CAR T cell therapy, CMC, and quality assurance.
- Demonstrated knowledge of the regulatory requirements in the design and conduct of clinical trials, drug development, and approval process, with a focus on IND and BLA processes.
- Must have previous experience in translational/ early development programs in oncology and hematology (e.g. successful IND and BLA submissions, FDA advisory committee meetings, oral explanations, pre-NDA/BLA, EOP2 meetings, international submission, etc.).
- Demonstrated ability to interpret and stay current with FDA and other international regulatory agency regulations and guidelines, with a successful record of development and implementation of the global regulatory strategy.
- Current knowledge and understanding of GxPs (GCPs, GLPs, GMPs).
- Extensive experience with FDA interactions, with proven track in biologics approval for oncology indications. Cell therapy experience desired.
- Familiar with eCTD and e-publishing systems.
- Experience in orphan drug development and approvals desired.
- Creative and strategic view in developing programs in immunology/ oncology and act as an advisor to the clinical team in regulatory and CMC quality.

QA Experience
- Experience in quality assurance, able and willing to contribute in setting up the quality system for clinical development including preparation of SOPs and gap analysis.
- First-hand experience in CMC quality assurance and in GCP quality.

Safety Experience
- Experience in safety reporting and working knowledge of pharmacovigilance.
- Intimate knowledge of safety reporting process.
- Able to manage the safety reporting process as needed.

Personal and Leadership Competencies
- Has a hands-on approach to preparation and submission of regulatory documents in a timely fashion. Project manages the regulatory and quality activities.
- Has the flexibility and willingness to solve problems that fall outside of immediate area of expertise.
- Excellent organizational, writing, communication, and time management skills needed to manage multiple ongoing projects simultaneously.
- Work independently in an interdisciplinary, fast-paced, often changing environment.
- Results driven, collaborative, and team-orientated.
- Strategic leadership skills, in high profile, complex or novel development programs.
- Ability to think strategically and critically evaluate risks to regulatory activities.

To Apply:

Eureka Therapeutics is an equal opportunity employer and does not discriminate against otherwise qualified applicants on the basis of race, religion, color, sex, age, ancestry, national origin, marital status, veteran status, medical conditions, handicap, physical or mental disability, sexual orientation, or any other status protected by law.

If you are interested in applying for this opportunity, please submit your resume or CV and cover letter to careers@eurekainc.com. All submissions will be evaluated, and interviews will be conducted for those applicants who most strongly fit our needs. If you are not contacted for an interview, your resume will remain on file and active for available positions for a period of one year.

No phone calls please and no agencies or recruiters.