Regulatory Affairs-Scientific Products Company (May 2023)

M.D. Degree Required

Estimated: $113K - $143K a year

Benefits

- Stock optionsPaid parental leaveDisability insuranceHealth insuranceDental insurance401(k)Paid time off401(k) 4% MatchParental leaveVision insurance401(k) matchingLife insurance

Qualifications

- Microsoft PowerpointMicrosoft WordMedicineMicrosoft ExcelMicrosoft OutlookDoctoral degree5 yearsComputer literacyWriting skillsFilingEnglishDoctor of PharmacyDoctor of PhilosophyComputer skillsProject leadershipDocumentation reviewCommunication skillsFDA regulationsTime management

Full Job Description

Humacyte, Inc. is bringing to market a once in a generation scientific technology platform, bioengineering readily available and universally implantable product opportunities focused on improving lives of patients and transforming the practice of medicine. Located in Durham, NC, the company develops and manufactures acellular tissues for the treatment of diseases and conditions across a wide range of therapeutic areas. The company's innovative technology supports tissue repair, reconstruction, and replacement while overcoming limitations in existing standards of care. Initially developing a portfolio of human acellular vessels (HAVs), to target multiple vascular markets including trauma, arteriovenous access for hemodialysis, peripheral arterial disease, and coronary artery bypass grafting. Humacyte is focused on the development of future markets such as pediatric heart surgery, delivery of cellular therapies, and multiple other novel cell and tissue systems.

We are looking for additional colleagues to continue to build our expanding team. Candidates will be expected to work both independently and collaboratively as part of the Humacyte organization. Applicants must be highly self-motivated, with solid communication skills, and demonstrates the ability to work in a team environment and lead other professionals and peers.

Position Overview:

This is a critical position in the regulatory affairs team, reporting directly to Chief Regulatory Officer. This position serves as Humacyte's liaison to the US FDA for assigned projects in clinical development. Internally, this role functions as Regulatory Lead and works with multi-disciplinary matrixed project teams to successfully meet project deliverables while adhering to regulatory requirements for programs and development products. This role also serves as a Regulatory strategist and is responsible for proactively developing and executing regulatory strategy for product in early and/or late stage of development.

Major Accountabilities:

- Co-Lead BLA submission effort across function
- Serve as regulatory strategist and regulatory project lead or co-lead for assigned project
- Accountable for establishing regulatory strategy for assigned project in US and global
- Monitor and interpret FDA and other health authorities' new policies and guidance, and assess the impact on company's business
- Could function as global regulatory lead, responsible for document preparation and interaction with other health authorities
- Might coach and mentor junior staff supporting the regulatory team
- Other responsibilities assigned when there is a business need

Specific Skills:

- Recent hand-on experience with leading BLA submission, preferably to FDA/CBER
- Recent experience with developing biologics
- Have demonstrated successful submission and secured approval of BLA/NDA from FDA
- Have functioned as FDA and other health authorities' point contact
- Have led formal meetings with FDA and other health authorities
- Familiar with FDA content and technical requirement for BLA submission
- Demonstrated experience developing and implementing regulatory strategies for US INDs, BLA, and/or NDAs
- Competent in leading across-function team and managing timelines
- Able to work under tight timeline and high stress situation

General Skills:

- Able to communicate effectively in English, both verbally and in writing
- Excellent communication and interpersonal skills
- Possess a positive roll-up-the-sleeves attitude and optimistic outlook
- Strong ability to work in a fast-paced team environment with fluctuating priorities, and collaborate effectively with others
- Excellent organizational and time management skills with ability to set own priorities in a timely manner
- High degree of flexibility and adaptability
- Basic computer skills required, such as knowledge of MS Word, Excel, PowerPoint, and Outlook
- Must be able to work as needed to meet tight deadlines and at peak periods
- Self-motivated and organized critical thinker with solid interpersonal and business communication skills
- Demonstrated ability to work in a cross functional team
- Adheres to company and facility specific policies and procedures, including SOP, training and meeting requirements
- Always observe safety precautions and regulations in all areas where duties are performed
- Responsible for reporting all safety hazards and potential unsafe working conditions
- Ensures Humacyte or other required trainings/certifications are up to date
- Represents the organization in a positive and professional manner

- Reports to work on time and as scheduled

Qualifications:

- Graduate Degree in Life Science is required. Ph.D, MD or Pharm D in Life Science highly preferred
- At least 5 years of regulatory project lead experience is required
- Experience leading a BLA filing is strongly desired

Perks:

- Stock Options
- 401k Plan with 4% Match and no Vesting Schedule
- Medical, Vision and Dental Plans
- Company Paid Long Term/Short Term Disability
- Company Paid Life Insurance
- 23 Days Paid Time Off (PTO)
- 10 Company Designated Holidays + 2 Floating Holidays
- Paid Parental Leave Policies