

Job Description Director/Senior Director Regulatory Affairs



Position: Director/Senior Director, Regulatory Affairs

Reports to: Senior VP, Regulatory Affairs

Job Location: Austin, Texas

Cassava Sciences, Inc.

Cassava Sciences is a publicly traded, clinical-stage biotechnology company based in Austin, TX.

Our current clinical development project is simufilam, a proprietary drug candidate to treat Alzheimer's disease. Simufilam is a small molecule (oral) drug with a novel mechanism of action. The drug candidate targets an altered form of the scaffolding protein filamin A. Altered filamin A occurs in the Alzheimer's brain and enables disease pathology. Simufilam restores the normal shape of filamin A to reduce disease processes and improve brain health.

In 2021, we initiated a Phase 3 clinical program of simufilam in Alzheimer's disease. In 2019 and 2020, we announced positive results of a Phase 2 clinical program of simufilam in patients with Alzheimer's disease. Clinical proof-of-concept was demonstrated by significant improvements in multiple cerebrospinal biomarkers in Phase 2 clinical trials.

For more information about us, please visit: https://www.CassavaSciences.com

Our Values

Company values matter. We value integrity, fairness, learning, performance and respect for all individuals at all levels of the organization. We strive to show a deep respect for all people inside and outside our Company, for our community, for science and for the patients and physicians we serve. We seek candidates who share in these core values.

Director/Senior Director, Regulatory Affairs

The Senior Director/Director of Regulatory Affairs is a new position. The person will be responsible for contributing to the overall regulatory strategy and tactics for the development programs at Cassava, and will assist in developing procedures to ensure regulatory compliance. *Please note this is a full-time, exclusive, office-based position.*

Responsibilities

- Develop, implement, and advise on regulatory strategies through all phases of development.
- Manage regulatory development projects, ensuring that the latest regulatory requirements and standards are met.
- Act as an advisor/liaison to senior management in order to plan, evaluate, and recommend regulatory strategies.
- Interface with Health Authorities, as appropriate, in regard to development, regulatory, and registration strategies.
- Manage assigned day-to-day regulatory activities, including the timely preparation and submission of regulatory documents to Health Authorities.



Qualifications and Experience

- BS degree in a scientific discipline is required; an advanced degree (Masters, PharmD, PhD) is desirable.
- Minimum 5 years of experience in Regulatory Affairs in an operating environment is required. Experience with FDA's Office of Neuroscience Division of Neurology is a plus.
- Comprehensive knowledge of applicable regulations and experience with requirements for IND/CTA, NDA/MAA, and interactions with Health Authorities is required.
- Proven ability to work successfully within a cross-functional team/partnership environment with a high level of ethics, accuracy and professionalism.
- Appointment as Director or Senior Director will depend on the level of experience.

We'd Like to Hear from You

For inquires and more information about the position, please email your CV in confidence to: Resumes@CassavaSciences.com

Cassava Sciences offers a comprehensive compensation package and a generous vacation policy. Company provides medical, dental, vision and life insurance and other employee benefits. Cash compensation is competitive with industry norms, and all full-time employees are offered stock options.

We participate in E-Verify and reserve the right to confirm prior positions, employers and educational levels. Cassava Sciences is an Equal Opportunity Employer (EEOC) and does not discriminate against any applicant for employment, or any employee because of age, color, sex, disability, national origin, race, religion, or veteran status.

Note regarding Covid. Our employees are fully vaccinated against Covid-19. If you are hired, prior to your start date you will be required to show evidence that you have received a Covid-19 vaccine or have a valid religious or medical reason not to be vaccinated in accordance with EEOC issued guidelines.

Important Fine Print

Beware of scams from individuals, organizations and Internet sites claiming to represent Cassava Sciences in recruitment activities. A formal recruitment process is required for all authorized positions posted by Cassava Sciences prior to issuing an offer of employment. This process includes an interview and never requires payment or fees from job applicants. If you receive a suspicious email message or phone call about recruiting on behalf of Cassava Sciences, do not provide any personal information or pay any fees. Interested candidates should apply to current openings only through Resumes@CassavaSciences.com. Cassava Sciences accepts no responsibility for costs or charges incurred as a result of fraudulent activity.

Notice to Agency and Search Firm Representatives

Cassava Sciences does not accept unsolicited resumes from agencies and/or search firms for any job postings. Without a valid, signed search agreement in place for a specific position listed, Cassava Sciences will not pay a fee to the agency or search firm in the event a candidate is hired for a position as a result of an unsolicited agency or search firm referral.