

Senior Director Regulatory Affairs

Description

Alpine Immune Sciences is a leading clinical-stage biopharmaceutical company dedicated to discovering and developing innovative, protein-based immunotherapies for autoimmune and inflammatory diseases. Exciting challenges lie ahead! Guided by our core values, we will meet these challenges. Join us! The Senior Director, Regulatory Affairs is a leader, who provides vision and direction in a fast-paced, dynamic, and competitive drug development environment. They report to the Executive Director of Regulatory Affairs and are responsible for contributing to the global company regulatory strategy and working closely with cross functional leaders in all regulatory interactions and activities for the development of Alpine's therapeutic candidates. Duties and responsibilities:

- Lead strategic regulatory activities to support cross functional product development teams in alignment with corporate and program goals.
- Serve as the global regulatory lead for select development programs.
- Develop and implement regulatory strategy for INDs, CTAs, BLAs; MAAs, NDAs; identify opportunities globally for expedited development.
- Provide strategic regulatory input on clinical, including therapeutic indication(s), study designs, patient populations, pediatric development; CMC; and nonclinical development.
- Prepare and coordinate authoring, review, and submission of high-quality regulatory documents, including Information Requests, IND/CTA submissions, BLAs/MAAs/NDA, Annual Reports/DSURs, briefing books for health authority interactions, clinical documents to ensure they are complete, well-written, and meet all relevant regulatory requirements. This may involve writing relevant sections of documents.
- Lead regulatory aspects of clinical study executing including management of correspondence with health authorities and coordination with partner companies and vendors.
- Ensure compliance of all Alpine activities with applicable global regulations, standards, and clinical practice guidelines.
- Monitor regulatory developments within the industry globally, evaluate impact to Alpine's programs, and provide actionable guidance to internal and external partners to adapt to and address the developments.
- Identify and communicate with senior management and cross-functional teams regarding potential regulatory issues; propose risk mitigation strategies and resolutions.
- Leads continuous improvement efforts on existing department processes and strategies, providing recommendations in areas of expertise.
- Supervise, mentor, and help develop the strategic and technical expertise of regulatory colleagues within the Alpine organization.

Qualifications:

- BS/BA degree (or equivalent) in a relevant scientific field required, with an advanced degree preferred.
- 10+ years of experience in biotechnology or pharmaceutical industry with hands on experience and knowledge of the drug development process and regulatory submission and approval process required.
- Experience working in a regulatory affairs leadership role with sole responsibility for a clinical-stage development program and marketing authorization applications, with experience as a manager/supervisor.
- Late-stage clinical development experience and experience submitting BLAs, NDAs, and/or MAA is required.
- CMC experience, including biologics, is desired.
- In depth knowledge of FDA, EMA, and ICH regulatory requirements and guidelines specific to the areas of clinical research, nonclinical testing, product development, and labeling is required.
- Must be capable of developing and implementing regulatory strategy and of managing complex negotiations with Regulatory Authorities.
- Demonstrated ability to develop/maintain strong working relationships with cross-functional internal and external teams, participate on and/or lead multifunctional teams, manage, and prioritize multiple projects and work independently.
- Prior global regulatory experience required; experience in Asia Pacific and Latin America is desired.
- Strong vendor management experience is

Hiring organization

Alpine Immune Sciences

Job Location

Remote

Base Salary

\$ 70000 - \$ 105000

Date posted

May 2, 2024

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desired. • Therapeutic area experience in autoimmune disease is desired. • Must be detail-oriented while also retaining the ability to see the big picture. • Must have effective technical/analytical skills to identify and solve problems independently. • Must be able to work in a fast-paced, timeline-driven environment. • Should have experience writing and developing SOPs.

At Alpine we engage equitable workplace strategies to ensure fair compensation. Actual compensation is dependent upon current market data, experience, and pay parity within our organization. This is a Director level position with a compensation range of \$230,000 to \$270,000. Note that there is a strong preference for candidates to be located in one of the following five states: CA, MA, NC, OR, or WA. We take care of our employees with a competitive benefits package that includes stock options, annual bonus, premium medical, dental, and vision coverage for employees and their dependents, as well as life and disability benefits, FSA, and 401(k) plans. We believe quality time outside the office is vital to our employees' satisfaction at work, so our flexible PTO plan of 160 hours, generous holiday time (generally 12 days), and parental benefits encourages team members to take time off so they can come back refreshed. Alpine team members enjoy competitive salaries and equity participation (stock options). Alpinists share a passion for meaningful work and are committed to solving the most complex problems in immunology to create new therapies for patients. We believe in innovative thinking, collaboration, flexibility, bias for action, and healthy debate. To foster our team of outstanding scientists and business professionals, we provide a premier work environment with a state-of-the-art lab and office spaces with truly inspiring views, and an open design to facilitate teamwork. Our treasured culture has been shaped by our diverse team who truly enjoys working and playing together. We nurture Alpine's culture in many ways, including all-company social events and happy hours, lunch-and-learn and education opportunities, interest groups like book club and movie nights, peer-to-peer recognition programs, a robust wellness program to help support physical, mental, and emotional health, and more. Alpine is committed to creating a diverse environment and is proud to be an equal opportunity employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, gender, gender identity or expression, sexual orientation, national origin, genetics, disability, age, or veteran status. Alpine is also committed to compliance with all fair employment practices regarding citizenship and immigration status. Our office and lab are located in the blossoming biotech neighborhood of Eastlake in Seattle. Alpinists enjoy the flexibility to work onsite, remotely, or a hybrid schedule, with evolving options as we prioritize keeping Alpinists safe and healthy. Onsite employees enjoy an open-office layout with comfortable huddle rooms and Zoom Room-enabled conference rooms, a spacious breakroom and kitchen with a coffee bar and snacks, and rooftop access to enjoy gorgeous views of Lake Union and Gas Works Park. Exciting challenges lie ahead, guided by our core values, we'll meet these challenges. Join us! Please mention the word ****LOVING**** and tag `RMzQuMTUwLjlyMy4yOA==` when applying to show you read the job post completely (`#RMzQuMTUwLjlyMy4yOA==`). This is a beta feature to avoid spam applicants. Companies can search these words to find applicants that read this and see they're human.

Contacts

Job listing via RemoteOK.com