



Job Title: VP, Clinical Development

Reports to: CMO

Location: Brisbane, CA

Summary:

Reporting to the Chief Medical Officer, the Vice President, Clinical Development North America will be a key member of the management team. Supporting senior leadership in achieving Aimmune's broader corporate objectives, including positioning the Company as a leading-edge development and commercial organization in oral immune desensitization therapeutics for food allergy. Based in Brisbane, California, the successful candidate will be responsible for leading and collaborating in the development of the strategy and design, and overseeing the execution and medical monitoring of all Aimmune-sponsored clinical trials. The successful candidate will oversee projects from pre-IND through Phase III.

As a member of a growing organization, the Vice President, Clinical Development North America will balance hands-on responsibility of managing clinical trial design and execution with mentoring a clinical team within the organization. S/he is excited to roll up sleeves and get deeply involved in study design, initiation and rollout, and has the reputation and presence to influence leading KOLs in the allergy and immunology space. The successful candidate will have the ability to assess emerging scientific and clinical development advances and assess these for the potential to provide new therapeutic options for patients, through innovative study design.

The successful candidate will provide leadership for the following areas:

- Partner across functional disciplines to produce the Biologic License Application and related submissions to relevant Regulatory Authorities
- Oversee the design and implementation of clinical development plans and protocols for Aimmune-sponsored clinical trials
- Lead, mentor and facilitate the professional development of the North American clinical science team to ensure comprehensive knowledge and training in pertinent fields
- Deliver medical oversight of all clinical studies in North America to ensure the timely and safe execution of trials
- Impart drug development knowledge and support study teams; participate in multidisciplinary meetings

- Provide local operational management for the North American clinical development teams to ensure close integration of clinical science, clinical operations and biometrics activities
- Contribute to the analysis, discussion and presentation of study results
- Work closely with EU clinical development leadership and global functional leadership to ensure an integrated approach to clinical development strategies that meet the goals of the company
- Develop strong relationships with investigators and key North American opinion leaders
- Optimize allocation of work to and contribution of Aimmune's development programs as a member of global medical leadership
- Participate in clinical aspects of interactions with Regulatory Agencies and corporate collaborators, especially in North America
- Provide medical input to the evaluation of Aimmune's portfolio and business development opportunities to allow determination of which assets address unmet medical needs

Candidate Profile

The Vice President, Clinical Development North America will have a strong medical orientation combined with business sense and pragmatism. Proven leadership skills including managing, developing and mentoring direct reports with the ability to inspire confidence, motivate and align a growing development team behind common goals. The successful candidate will have a track record and demonstrated success of advancing biologic programs through late stage development. S/he will have an entrepreneurial bent and action orientation that fits with a growth-oriented company.

S/he should demonstrate superior analytical and organizational skills with the ability to manage multiple projects effectively and simplify large amounts of complex information to draw valid conclusions. The successful candidate should have excellent communication skills with the ability to collaborate and influence colleagues across all levels of the organization.

The ideal candidate will bring both breadth and depth of clinical experience from IND phases, however, experience weighted towards late development Phase II/Phase III is highly valued. The essential functional capabilities include regulatory affairs, safety, process manufacturing and project management.

S/he will also serve as a credible spokesperson for Aimmune with a wide range of audiences, such as investors, partners and academic collaborators.

In terms of the performance and personal competencies for the position, we would highlight the following:

Education and/or experience:

- Medical degree and experience in patient care are required
- Additional training/experience in clinical immunology and allergy or other immunological disease areas preferred, but not required
- At least 10 years pharmaceutical or biotechnology industry experience in clinical development including the leadership in late-stage clinical development and support of BLA filings
- Experience with oral biologic therapeutic modalities and/or pediatric trials a plus
- Experience with clinical development for a novel product through a marketing authorization
- Thorough understanding of GCP
- Ideally, having previous experience of negotiation with FDA and a good understanding of US regulatory requirements; global experience a plus

Attributes of the ideal candidate:

- Dedication to patient safety
- Commitment to a collaborative and accessible work style, having low ego
- Heavy execution focus on goals and timelines
- Ability to absorb new information quickly and gain command of relevant literature
- Preference for working in a fast-paced, team-oriented, environment
- Desire for new professional challenges
- Possessing excellent problem-solving and decision-making skills; strives for appropriate balance between taking initiative and seeking input from others
- Ability to analyze and summarize complex data and information concisely
- Demonstrated strong people and team leadership to contribute at the highest levels in a company, both up and down the organization
- Excellent collaborator and communicator, both locally and globally with peers and leaders across the organization
- Excellent written and verbal communication skills

Leadership attributes include:

Setting Strategy

- Ability to create and articulate a vision; a demonstrated track record of translating broad strategies into specific objectives and action plans;
- Demonstrated ability to align personal, team and/or department goals and objectives with organization goals and business strategy; set priorities and allocate resources to achieve them;
- Proven ability to foster a culture of engagement by communicating with clarity, transparency and honesty; track record of seeking multiple perspectives and other points of view.

Executing for Results

- Proven track record of consistently delivering on commitments; demonstrates ownership of results within (and beyond) his/her area of responsibility; sets clear and high expectations and holds self and others accountable for decisions and results achieved;
- Track record of developing and applying unique ideas and new methods to achieve higher performance and excellence;
- Entrepreneurial predisposition, excited to “roll up the sleeves,” and demonstrating a strong work ethic.

Leading Teams

- Ability to establish and maintain a functional-area operating culture that supports performance excellence, quality, integrity and teamwork; excellent understanding of team processes and dynamics;
- A demonstrated track record in attracting, selecting, coaching, mentoring, developing, and retaining talent; history of managing high performing, diverse teams;
- Natural ability to seek and welcome feedback; responds well to coaching; skilled in providing frequent feedback and coaching to others on ways to improve performance; recognizes and celebrates success;
- Positive attitude that creates engagement, excitement and personal investment in others; track record of fostering continuous improvement, innovation and risk taking; adapts to and/or drives positive change.

Building Relationships and Using Influence

- Significant experience interacting, managing, and influencing senior management and regulatory bodies;
- Proven track record of working successfully across organizational, functional, and geographic boundaries to achieve company goals;
- Builds and maintains strong relationships with team members, other functions, strategic partners and customers; works cooperatively with others to meet common goals.

About Aimmune Therapeutics, Inc.

Aimmune Therapeutics is a clinical-stage biopharmaceutical company located in Brisbane, California, in the biotechnology hub south of San Francisco and in Kings Cross, London, United Kingdom. The company is developing desensitization treatments for food allergies and will complete an International Phase III trial for its lead product, AR101, for the treatment of peanut allergy, in late 2017.

For more information, please visit www.aimmune.com

Aimmune Therapeutics offers a competitive compensation and benefits package.
Aimmune Therapeutics is an Equal Opportunity Employer.

Qualified candidates should forward a resume and cover letter, including a statement of interest, availability, and experience to Human Resources (careers@aimmune.com) with the job title in the subject line.