



Position: Head of Commercial Compliance

Reports to: General Counsel

Location: Brisbane, California

Summary

Reporting to Aimmune's General Counsel, the Head of Commercial Compliance is responsible for the development and administration of programs, policies, and practices to ensure the company's compliance with applicable healthcare laws and regulations. The incumbent will have experience creating a comprehensive compliance program from scratch to enable biopharma companies to be fully compliant for a first product launch. The Vice President of Commercial Compliance will be influential in fostering a culture that builds and supports the understanding and appreciation of compliance as a value.

Specific Responsibilities:

- Advise senior management, the Board of Directors and partner with the business to create a compliance program
- Lead the compliance committee and lead the creation of policies, SOPs and subcommittees to build out the compliance program
- The candidate will be an expert in advising on the Anti-kickback statute, false claims act, healthcare professional disclosure laws, OIG Guidances, the PhRMA code, FCPA and privacy laws (including HIPAA and GDPR)
- The candidate will develop, implement and maintain compliance activities including internal policies, procedures and committees (when relevant) for the following:
 - Training and preparing medical affairs liaisons for field deployment
 - Training and preparing sales force for deployment
 - Transparency reporting
 - HCP contracting, including FMV rates and tiering
 - Review of promotional materials
 - Sponsorships
 - Grants
 - Codes of conduct
 - Medical education
 - Publication planning ad review
 - Investigator initiated studies
 - Patient group collaborations
 - Expense reimbursement
 - Market research
 - Pricing
 - Disease awareness

Qualifications / Requirements:

- 10+ years' experience practicing law including in-house experience in a biotechnology or pharmaceutical organization required

- Recent industry experience building and leading the Commercial Compliance function
- Demonstrated knowledge and understanding of the requirements for effective compliance programs as set forth in OIG Guidance and the Federal Sentencing Guidelines
- Demonstrated knowledge and understanding of the legal and regulatory framework affecting the pharmaceutical/biotechnology industry; including, but not limited to, sales and marketing, medical affairs, fraud and abuse issues, OIG and other industry guidance documents, Anti-Kickback Statute
- Demonstrated effectiveness operating in complex organizational and regulatory environments
- Demonstrated application of business judgment in solving legal problems
- Self-starter, ability to work with minimal supervision
- Strong drafting skills
- Strong interpersonal and communication skills
- Ability to collaborate and function well in a team environment
- Customer service oriented, pragmatic and proactive approach to work

About Aimmune Therapeutics, Inc.

Aimmune Therapeutics is a clinical-stage biopharmaceutical company founded to address the unmet medical need in food allergy, which currently has no approved treatments. Our mission is to improve the lives of people with food allergies, based on our proprietary desensitization treatments in development. Aimmune's recently announced positive top-line data from its pivotal Phase 3 PALISADE trial for AR101, the company's lead investigational drug for peanut allergy. Headquartered in the heart of San Francisco's biotechnology hub, Brisbane, California, Aimmune has additional offices in the Kings Cross area of London, and in Raleigh, North Carolina.

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.

Aimmune Therapeutics is an Equal Opportunity Employer.

Principals only; no recruiters please.