

Position Description: Vice President, Regulatory Affairs

Aratana Therapeutics, Inc. (NASDAQ: PETX), a pet therapeutics company focused on the licensing, development and commercialization of innovative therapeutics for dogs and cats, is a fast-growing company headquartered in the greater Kansas City area. Aratana intends to become a leader in pet therapeutics by developing, manufacturing and marketing therapeutics that address unmet or underserved medical needs of pets. The Aratana approach to pet therapeutics is built around bringing the best in scientific advances from human science to veterinary medicine.

In 2016, we have received FDA approval for three innovative therapeutics:

- A prostaglandin receptor antagonist that specifically targets the EP4 receptor to target osteoarthritis pain and inflammation in dogs
- A selective ghrelin receptor agonist that mimics ghrelin, the naturally-occurring “hunger hormone,” to stimulate appetite in dogs
- A long-acting, local anesthetic that provides up to 72 hours post-operative pain relief following cranial cruciate ligament surgery in dogs

Aratana is currently making two of the FDA - approved therapeutics commercially available to veterinarians. In addition, Aratana is working on a broad portfolio of other therapeutic candidates and continues to seek in-licensing opportunities.

Following the recent FDA approvals, Aratana has established sales, veterinary medical liaison and pharmacovigilance teams. During the coming years, Aratana anticipates continuing to expand its commercial activities.

The Vice President, Regulatory Affairs oversees all of the company’s interaction with the US Food and Drug Administration’s Center for Veterinary Medicine (FDA CVM) and the European Medicines Agency (EMA). The position is based in Leawood, KS and reports to the company’s Chief Development Officer. Limited domestic travel is required.

Key Responsibilities

- Serve as the company liaison to the CVM Office of New Animal Drug Evaluation (ONADE) and Office for Surveillance and Compliance (OS&C).
- Oversee all non-manufacturing pre-approval and post-approval submissions.
- Assist the Project Managers in compiling INAD submissions.
- Overall responsibility for compliance of all promotional materials with current regulations.
- Assemble and file all Drug Experience Reports in cooperation with Pharmacovigilance and Quality Assurance.
- Work with pharmacovigilance team to ensure accurate and timely adverse event filing with FDA CVM and EMA.

- Train and educate the entire organization on regulatory compliance with applicable regulations.
- Maintain and manage the electronic regulatory submission system via the ESG.
- Maintain the company's state licenses.
- Represent the company at the Animal Health Institute (AHI) Animal Drug Section (ADS) and coordinate the company's presentation and participation in AHI's working groups.

Skills and Key Competencies:

- Minimum of ten years in animal health industry in product development, regulatory affairs and/or quality assurance in FDA regulated pharmaceuticals.
- DVM/VMD preferred, though other degrees in life-sciences with relevant industry experience will be considered.
- Proficient in technology systems, including Microsoft Office Suite, PV database systems and ESG.
- Ability to interact with key internal stakeholders: Marketing, Manufacturing, Quality Assurance, and Product Development to flourish in a small, rapidly growing company environment.

Compensation will be determined based on industry benchmarks and individualized to the candidate and will include annual base salary, potential for annual bonus and equity. Full benefits package provided.

Aratana is an equal opportunity employer and all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, national origin, disability status, protected veteran status, or any other characteristic protected by law.