Job Title: Senior Regulatory Affairs Associate

Diamond Animal Health is a leader in contract manufacturing of animal pharmaceuticals and vaccines. Based in Des Moines, the company operates a USDA-, FDA- and DEA-approved facility. Diamond offers comprehensive services such as Research and Development, Regulatory and Licensing Approvals, Contract Manufacturing and Logistics.

Job Summary: This role will oversee regulatory support and compliance in accordance with guidelines from USDA, FDA and international regulatory agencies. This position involves responsibilities related to new product development and the management of controlled documents.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

- Communicate with government agencies (such as USDA and FDA) and current or potential business partners regarding regulatory matters.
- Provide necessary documentation to distribution partners and international government agencies for product registration or maintenance of registration.
- Support the process of new product licensing.
- Apply for or renew permits to receive or regulated materials.
- Apply for or renew permits for international exportation of products.
- Collaborate with various departments to plan, organize, conduct and monitor clinical trials and testing.
- Develop protocols and prepare final reports for clinical trials.
- Review, update and draft new Standard Operating Procedures (SOPs) within the Regulatory Affairs Department as needed.
- Review and prepare outlines of production and special outlines.
- Develop and revise ASR/Sampling Plans for raw materials, in-process products and stability programs.
- Work with departments to determine specific information requirements for each ASR/Sampling Plan.
- Prioritize Document Control submissions and lead the document review process for timely approvals.

- Provide guidance to other departments on regulatory and in-house requirements for documenting incoming raw materials and approving new vendors.
- Distribute Materials of Origin (MAO) surveys to evaluate raw materials and new vendors.
- Review existing MAO Surveys to determine if updates are needed.
- Collaborate with departments to streamline processes and enhance interdepartmental communication for evaluating and approving new MAO and vendors.
- Organize and maintain a system to track seed and cell records (master, working and production seeds) for easy tracing of final product lineage and MAO.
- Conduct inspections and audits related to MAO issues and seed/cell tracing.
- Stay current with 9 CFR, 21 CFR, and other applicable regulations.
- Provide training for Regulatory staff.
- Manage new product development initiatives.
- Support Quality Assurance efforts.
- Perform other assigned duties as required.

EDUCATION AND/OR EXPERIENCE:

- Bachelor's degree in biological sciences required; Master's degree preferred.
- Experience or special interest in new business development, statistical analysis, document control, clinical trials, USDA and FDA regulatory support, technical writing and research and development is advantageous.

KNOWLEDGE, SKILLS AND ABILITIES:

- Proficient in understanding and adhering to USDA/FDA regulations.
- Skilled in leading interdepartmental meetings for instruction or collaboration.
- Capable of comprehending, evaluating and applying internal processes and procedures, with the ability to suggest improvements.
- Demonstrates excellent customer service skills for both internal and external stakeholders, including active listening, analysis of requests and needs and providing timely resolutions.
- Effective and professional communication skills, both verbal and written.

- Intermediate proficiency with Microsoft Office Suite, internet software, email and electronic document control systems.
- Maintains confidentiality, with appropriate disclosure to key individuals as necessary.
- Ability to read, write and speak Spanish (preferred but not required).
- Maintains confidentiality while appropriately disclosing information to key individuals.

PHYSICAL DEMANDS:

- Requires prolonged sitting, some bending, stooping and stretching.

WORK ENVIRONMENT:

- Typical office environment.
- The noise level in the work environment is usually moderate.

Diamond Animal Health is an Equal Opportunity Employer

Benefits:

Diamond Animal Health offers a comprehensive benefits package to our employees, including:

- Health Insurance (Medical, Dental & Vision).
- Company-Paid Life Insurance with AD&D.
- Company-Paid Short-Term and Long-Term Disability Insurance.
- Employee-Paid Voluntary Life Insurance Options.
- Retirement Plan (401k Traditional and/or Roth) with Company Match.
- Paid Time Off (Vacation, Sick, and Holidays).
- Family Leave (Maternity and Paternity).
- Training and Development Opportunities.