POSITION TITLE:	Manager/Sr. Manager of Regulatory Affairs
DEPARTMENT:	Regulatory Affairs
POSITION REPORTS TO:	Director, Global Regulatory Affairs
WORK SCHEDULE:	Monday – Friday with ability to flex as needed

COMPANY OVERVIEW:
Phibro Animal Health Corporation is a publicly traded organization with a rich history spanning nearly 100 years of service. The Company is a global manufacturer of medicated feed additives, feed ingredients, advanced nutrition solutions and vaccines. Phibro's revenues are in excess of $750 million, and are supported by approximately 1400 employees worldwide.

POSITION DETAILS:
The Regulatory Affairs Manager will be an integral part of our Global Regulatory Affairs team based out of our Corporate Headquarters in Teaneck, NJ. Responsibilities of the role include but are not limited to the following:

Key Responsibilities:

- Preparation, submission and maintenance of the Chemistry, Manufacturing and Controls (CMC) technical section of veterinary drug submissions supporting our global business including:
  - new drug submissions
  - supplemental submissions
  - annual reports
  - response to US FDA-CVM and other agency deficiency letters
  - preferred but not required: pharmacovigilance reports
- Initiation and maintenance of Veterinary Master Files, VMFs/Drug Master Files, DMFs.
- Primary contact for electronic submissions specifically:
  - structured product labeling (SPL) including
    - drug listing
    - establishment registrations
- Assist in the development and execution of Regulatory Plans.
- Assist in the regulatory strategy to obtain new approvals.
- Liaise with Phibro Animal Health (PAH) project teams; including Manufacturing, Product Development and the Quality Unit to facilitate the receipt of requested deliverables.
- Represent PAH on relevant Animal Health Institute (AHI) industry committees. (AHI is the leading veterinary pharmaceutical trade association for the USA)

Accountabilities:

- Ensure the timely submission and maintenance of original or supplemental veterinary drug submissions.
- Ensure the timely submission of original, amendments and updates to VMFs
- Ensure the timely response to US FDA-CVM queries or deficiency letters
- Support overseas PAH regulatory staff for global submissions, and other regulatory interactions

Technical Skills:

- Scientific background with proven success using this technical / scientific background to solve regulatory issues.

Key Competencies Required:

Personal:

- Excellent communication and organizational skills demonstrating the following attributes:
  - strong time management skills
  - proactive and self-motivated
  - attention to detail
  - problem solving skills; able to "think outside of the box" to generate potential solutions
  - excellent interpersonal skills with a "team" mind set
- Ability to take ownership of assigned projects from beginning to completion
- Commitment to the position and to Phibro demonstrated by willingness to work outside of the normal working day when required by the work load and/or project.
- Good negotiation skills

Experience:

- 3 to 5 years' experience in Regulatory Affairs
- Prior experience initiating, submitting and maintaining original and supplemental applications for either veterinary or human finished products. Experience with medicated feed additives an advantage
- Experience Mineral Nutrition & Nutritional Specialties a plus

Education:

- Bachelor of Science in a scientific discipline required

Travel:

- Domestic Travel: Less than 10% per year to attend Animal Health Institute (AHI) / Industry / FDA meetings or to meet with other Phibro subsidiary personnel.
- Ability to travel internationally desirable

Interested candidates can send resumes to humanresources@pahc.com with "Regulatory Affairs – Teaneck" in the subject line.