

Senior Director of Regulatory Affairs

Location: Blacksburg, VA
Salary: Commensurate with Experience

Employment Status: Full-Time
Travel Required: 25%

Please submit resumes to hr@nrpharma.com
Subject Heading: Senior Director of Regulatory Affairs
Fax: (540) 633-7939

JOB SUMMARY:

New River Pharmaceuticals Inc. (NASDAQ: NRPH) is seeking an experienced individual to fulfill Senior Director of Regulatory Affairs and project management responsibilities.

ESSENTIAL DUTIES AND RESPONSIBILITIES include the following:

The ideal candidate will have the professional and personal credentials to take an immediate leadership position in directing the regulatory strategy for the candidates in the pipeline .

The person will be responsible for providing regulatory guidance to cross functional teams and also provide guidance and training to direct reports.

Additional duties and responsibilities that may be assigned from time to time

QUALIFICATIONS To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The qualifications listed below are representative of the knowledge, skill, and/or ability required or desired.

- Comprehensive knowledge of current FDA regulations and guidelines
- Solid working knowledge of US pharmaceutical regulations, and good manufacturing, clinical and laboratory practices
- Effective verbal and written communication skills.

EXPERIENCE

- 7-10 years direct, industry-related regulatory experience in pharmaceuticals, biopharmaceuticals or the biotechnology industry
- Minimum 5 years experience in a senior regulatory role with demonstrated success in project management and strong budget management experience.
- Extensive experience interfacing with regulatory agencies
- Experience in the preparation of IND and NDA submissions for drug products
- Solid regulatory filing experience in either drugs or biologics

EDUCATION, CERTIFICATION, LICENSES and/or REGISTRATIONS

- MS/MBA or PhD. required

New River Pharmaceuticals Inc. is an equal opportunity employer.