



REGULATORY AFFAIRS CONSULTANT

Scientific & Regulatory Consultants, Inc. (SRC), a national consulting firm for the antimicrobial industry, is seeking an experienced Regulatory Affairs Consultant to join their consulting staff. Eligible candidate must relocate to Northeast Indiana.

SRC specializes in providing an understanding of the regulatory and scientific issues relating to the testing, registration, and marketing of EPA and FDA antimicrobial/pesticide products.

Successful candidate will be in a consultative role to many of the leading companies in the world and will play a vital role in proactively carrying out the day-to-day activities of the team.

Depending upon experience, the full time consultant position may be responsible for or assist with:

- Preparation of EPA/FDA submissions.
- Providing interim responses and negotiations as needed.
- Regulatory strategy and direction for clients.
- Staying abreast of national and international regulatory issues. Recommend client responses as needed.
- Regulatory support to client research & development, marketing, sales, customers, management, etc.
- Reviewing label/technical reports for regulatory compliance.
- Scientific review of substantiation for labeling and advertisements
- Preparation of claims and supplemental literature.
- Reviewing safety data
- Acting as liaison to EPA/FDA and other regulatory agencies.
- Providing external training for clients
- Creating/reviewing SOPs and validation documentation
- EPA state registrations and state issues.
- GLP and GMP audits and interpretations.
- Trade association participation
- Estimated travel – 0 to 4 overnight trips/month.

Knowledge and Skills:

- BS Technical Degree
- Previous experience meeting directly with government regulatory agencies preferred
- General knowledge of EPA/FDA GLP and FDA GMPs
- 5+ years of experience in regulatory affairs
- Strong working knowledge of EPA and FDA regulations and standards a plus
- Knowledge of Canada and EU regulations a plus.
- Strong leadership skills, excellent written and verbal communication skills and attention to detail required
- Innovative problem solver
- Basic computer skills including Windows, Microsoft (i.e. Word, Excel, PowerPoint)

Compensation:

- Starting salary commensurate with experience
- Bonus incentive program
- Health insurance available
- Pension benefits
- Friendly work environment with relaxed dress code.

Send your resume electronically to pzook@srconsultants.com or via mail: P.O. Box 1014, Columbia City, IN 46725.