

“High standards, attention to detail, meeting deadlines...”

Bio-economy Career Profile

Position: Regulatory Affairs Specialist / Safety Officer

Name: Karen Long

Company: Angiotech Pharmaceuticals, Inc.

Salary Range: Salary is commensurate with qualifications and experience

What I do:

The regulatory affairs function serves as a liaison between the company and a regulatory authority, such as Health Canada or the Food and Drug Administration (FDA). I am the last person on the team to check the data before it goes to the FDA for approval. If the project team can convince me that the product dossier is consistent and complete, then I can convince the FDA.

My days vary, but the work can be divided into thirds: reviewing documents, attending meetings, and writing reports. As the company safety officer, I also do inspections, work with external contractors, and investigate funny smells!

What education and skills do candidates need for this position?

I have a Bachelor's degree in chemistry and a Masters in Pharmaceutical Science.

There is no specific training for this job. People tend to fall into this role “by accident.” Some people have a life science background, but mainly they come from physical sciences or engineering.

In this job you get to learn a little bit about everything (chemistry, manufacturing, preclinical and clinical research). People who work in this position should love to write, which is something many scientists don't enjoy. Diplomacy is another useful skill; you need to be able to persuade without being offensive.



You should have high standards, attention to detail, and the ability to meet deadlines. It's not uncommon to have several people working on different sections of a project, so you need to be able to bring it all together and have each section consistent with the others, while meeting the deadline.

You require good grammar and an understanding of the technology you are helping to develop. Computer programming is fast becoming a useful skill, as many Regulatory Authorities are now asking for electronic submissions. Lastly, you need to learn and interpret the regulations for all of the countries in which your company is doing business, and teach them to your team.

What are the best parts of your job?

You know your work will help people, and there is no greater feeling than that.