



Canadian Association of Professionals in Regulatory Affairs

Association canadienne des professionnels en réglementation

STUDENT RELATIONS COMMITTEE INFORMATIONAL INTERVIEW

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| REGULATORY AFFAIRS PROFESSIONAL PROFILE OF | Interviewee: |
| | AUSTIN NAM |
| | SENIOR REGULATORY AFFAIRS ASSOCIATE |
| | BAXTER HEALTHCARE CORPORATION |
| Student Author: Mallika Pillai | Date of Interview: May 07, 2013 |

The following questions and responses were asked to create a profile of a RA professional, including the activities performed as part of regulatory affairs work and background educational and career pathway information, as well as to obtain advice for students entering the regulatory affairs profession:

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| Question: | How did you get into Regulatory Affairs? Can you describe the career path you took to get to your current position? |
| | I completed a Bachelor of Science and a Master of Science at Queen’s University. When I left university, I spoke with several people in the pharmaceutical industry and learned about Regulatory Affairs. I decided that this was something I was interested in pursuing and found that that the post-graduate regulatory affairs programs were a quick way to enter the field directly. |
| Question: | What features of your RA program have been most useful in your job? |
| | The RA program gives you enough information so you can speak the language when you get your first start. The RA field often speaks in acronyms and it can be challenging for the uninitiated to follow along. Coming out of the program, I was also familiar enough with the general guidelines and regulations to be able to function without too much supervision. Without that background, I think the learning curve can be steeper. |
| Question: | What were your biggest challenges to obtaining an internship and how did you overcome them? |
| | I was one of the fortunate ones to land an internship quickly but I had my worries like everyone else. I think my biggest concern was a lack of prior industry experience. I made a concerted |



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effort to tailor my resume with the most relevant skills and experiences and tried to be as prepared as possible for my interviews.

Question: What are some of the desirable traits/useful skills for your position and in RA?

Written communication is an often used skill in this role. A lot of communications are done through written documents. It becomes very important to convey your message clearly and concisely.

Question: With which other departments or functional units within your company do you regularly interact with?

The most common functional areas I work with are Quality, Marketing, Medical Affairs and Clinical Development. I may also work with various functions within the manufacturing plant on a project to project basis.

Question: How was your transition from school into RA?

The pace was much faster than school and there was a lot less support. The situations I encountered in RA have also been much more ambiguous. The scenarios that were presented in school were fairly black and white with a rather obvious solution. It doesn't work out that way very often in the industry.

Question: What are the typical duties in a junior RA role?

Over the years, I have often seen interns and junior associates work on pieces of a submission, updating compliance files, reviewing labelling artwork, revising SOPs and supporting internal projects.

Question: What kind of experience, paid or unpaid, would you encourage for anybody pursuing a career in this field?

Any type of industry experience is, of course, helpful to getting started. If you have experience that can demonstrate an analytical ability, leadership skills and strong communication skills,



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these are good attributes to show to prospective employers.

Question: How are work teams or groups organized?

It varies depending on the organization. Some organizations will group teams based on activity such as clinical vs. CMC submissions or pre-approval vs. post-approval. In my current organization, we are organized by business franchise.

Question: What advice would you give to students applying for internships? During their internships?

Pay careful attention to your resume and be prepared for your interviews. During your internship, soak up as much experience as you can and don't be afraid to approach people. Everyone always looks busy in RA...don't let that be a barrier to you.