Association **c**anadienne des **p**rofessionnels en **r**églementation

Canadian **A**ssociation of **P**rofessional **R**egulatory **A**ffairs

STUDENT RELATIONS COMMITTEE INFORMATIONAL INTERVIEW

REGULATORY AFFAIRS PROFESSIONAL PROFILE OF	**Interviewee:**
	JUDITH HALMOS-STARK
	ASSISTANT VP, REGULATORY AFFAIRS
	WYETH - PFIZER
Student Author:	**Date of Interview:**
Aaron Yu	June 28 2010

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:

Question: ***Can you pick a day from last week (or this week depending on when the interview is taking place) and describe what your work day/schedule was like? What did you have planned for the day? What did you encounter that was unplanned?***

The nature of Regulatory Affairs is that there is never total predictability in terms of the day's schedule. There is a need to manage issues inside and outside the office. For example, last week, I had to deal with an issue that arose in the United States with a product. Being a global company, I had to quickly assess the situation and determine its impact to Canada and handle it accordingly. With globalization, it becomes important to keep abreast with your product all over the world so you can assess if there's an impact to the Canadian marketplace and deal with Health Canada.

Another aspect is responding to Health Canada questions and comments during the review of a filing. For example, we had two different clarifaxes, for two different submissions. Then there's the question of getting experts together within local and global organizations to discuss and strategize: how we're going to respond to those questions, who is going to respond, timelines to respond. So we need to have a game plan. Basically, in my position, it is a question of providing the leadership in terms of ensuring that the department is operating effectively and efficiently. This includes addressing any issues that haven't been resolved before they get to my level. For example, a Regulatory Affairs Project Manager can handle daily tasks, but if there's an issue that arises from Health Canada, i.e. timeline is not good for company because the deadline can't be met, I would have to get involved to deal with issue. Thus, any issues that would percolate up to my level would have to be dealt immediately with to ensure efficiency.

Question: ***How did you get into Regulatory Affairs? Can you describe the career path you took to get to your current position?***

Regulatory Affairs didn't exist when I started. I started in industry 35 years ago in Quality Assurance/control. I moved to Toronto from Montreal and discovered a lot of manufacturing, etc. doesn't exist here to the same extent. I discovered a scientific affairs area of a pharmaceutical company and started with them.

At the time, it was a smaller area; not so specialized 35 years ago. So I did a little bit of everything: clinical trials, medical information, product information, and regulatory, etc. As regulatory requirements

became more complex and stringent, the official role of Regulatory Affairs was being formed. It was really a response to the ongoing requirements from Health Canada. Before that time, various people (from operations, etc. – no dedicated personnel) from companies (varied from company to company) dealt with the submissions and their regulatory aspect. That's how the profession came about - from people who responded and liaised with Health Canada.

As the company grew, I grew with it and gained successively higher levels of responsibility. Also, I must say that, although the basics of RA are taught now in schools, I believe that formal education must be coupled with experience. I believe that experience is the best teacher because what the schools talk about is what the regulations and policies are, but Health Canada is there to interpret the regulations and policies. So one must really understand their mindset and have that relationship so that both parties can be on the same page. Just like any relationship building – it comes with experience. Policies/guidelines are continuously changing and must be kept up with when you're in this field. I am a big supporter of the profession of RA and feel that it's good to get the basics in school.

Question: Would you consider going back to working in Quality Assurance?

No, my niche has been RA for a long time. It suits my nature; I like the dynamic, changing environment. It enables you to see the whole picture in drug development - not being an expert, but the one that puts it all together.

Question: How often do you travel (if at all) for conferences, meetings, etc.?

I think that at the beginning of one's work experience in a company, there's more travel involved as you build experience and relationships within company and with Health Canada. Once established though, it's not as necessary to travel so much. You don't have to be there eye-ball to eye-ball because relationships already formed – with time, travel can be minimized. I think this applies to any kind of business: you want to be there the first time to see and connect to people, whether internally or externally. Over time, when you feel that this has been built up, you can use the telephone instead. It essentially changes with time. There is more travel in the beginning of starting at a company. In my current position, travelling is at maximum, twice a month. The types of meetings I attend would be internal (to different company sites) and to Health Canada.

Question: What features of your education/formal training are most useful in your career?

You definitely need a scientific background. RA is per se, regulatory science. What educational level? It's open. You need to understand the various components. You don't need to be expert in toxicology, for example, but you need to understand what you're looking at in terms of toxicology. You need good interpersonal skills because you're dealing with so many different people internally and with Health Canada. You need very good writing skills because communication with Health Canada is mostly in writing and you must be very clear. If you're not clear? You're liable to get a clarifax from them. One can become more efficient if the writing is clear because it can minimize the questions received from Health Canada that necessitate a response. And in addition to all of those things, you need to be detailed oriented. If don't like analyzing data, RA is not for you. You must enjoy analytical thinking.

Question: To how many industry and professional associations do you belong? How have they been helpful to you in your career?

I was one of the founding members of CAPRA. The reason I participated in founding CAPRA was because I thought it was critical for RA professionals to have an association in order to professionalize themselves. So CAPRA was set up so that it's an educational forum and allows for professionals to

interact.

I am also a member of, and used to go often to, American Medical Writer's Association – one can take courses and get certification in medical writing. In fact, I am a certified medical writer. Medical writing is critical. It is critical for one to write correctly and concisely. It's a huge factor, especially with the increasing prevalence of electronic files. A lot of the younger professionals seem to be lacking the ability to communicate on an official level in writing.

I also attend various scientific symposiums. For example, if there is an oncology product in the pipeline, I might want to go to a symposium on that subject matter to make sure I am updated on the therapeutic areas that are of interest to the company i.e. keep up to date on science behind drugs that are in development.