CAPRA ACPR

Canadian Association of Professionals in Regulatory Affairs

Association canadienne des professionnels en réglementation

STUDENT RELATIONS COMMITTEE INFORMATIONAL INTERVIEW

REGULATORY AFFAIRS PROFESSIONAL PROFILE OF	Interviewee:
	DOMINIQUE LANIEL
	REGULATORY AFFAIRS ASSOCIATE
	ABBVIE

Student Author:	Date of Interview:
Ginny Kwan	April 09, 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:

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

I did an undergrad in Biochemistry at Université de Sherbrooke. I continued to grad school but while doing fundamental research in the lab, I started looking for another option. I applied to the DESS in drug development at Université de Montreal (U de M) in the Clinical Research option because I liked the idea of staying in research but working in a more applied setting. However during the admission interview I was oriented towards the Regulatory Affairs option instead, because the coordinators felt that my personality would be a better fit for this field. The options were similar but this was already a shift for me towards RA. At the end of the DESS, I did an 8-month internship in regulatory affairs in a pharmaceutical company, which lead to a M.Sc. in Pharmaceutical Sciences from UdeM. I consider both the knowledge gained during the DESS and the practical aspects learned during my internship were instrumental in promoting myself for my first job as a regulatory affairs associate.

Question:	**What features of your RA program have been most useful in your job?**

The DESS at Université de Montreal is really focused on teamwork. Most of the people in the program come from scientific backgrounds or are healthcare professionals and therefore have a

very technical education. This program is structured with projects and teamwork, which puts the students into situations where they have to be organized, show leadership skills, deal with the opinions of others, discuss and negotiate to come to an agreement. This was really helpful during my job interviews because I had examples to give when I was asked about a situation where I had to negotiate/sell my point of view. Another great feature is the teachers, because they work in the industry and are subject matter experts. It gives you a sense of what is going on outside of the university. Finally, the opportunity to pursue the M.Sc. and do an internship in the industry is great to gain hands-on experience. I really feel that this program is centred on the needs of the industry.

Question:	**What areas/features of the RA industry are the most interesting to you?**

From what I know of RA, I find it very interesting to be part of something bigger and having a key role in the whole cycle of bringing a product to market or keeping it there. I also like the interactions we have with other groups such as commercial, marketing and quality assurance.

Question:	**What skills were most valuable in your first role? With what other departments or functional units within your company do you regularly interact with?**

Attention to detail and analytical skills are really important. For example you get documents from the global company to support a change in the formulation of a product. As a Canadian affiliate, you need to have it approved by Health Canada. So you have to dig into the supporting documentation and determine if it is compliant with what we need in Canada. A small detail might be very important and you have to make sure it's there. Good communication skills are also a must.

Quality Assurance is very important for CMC (Chemistry, Manufacturing and Controls) changes, so we have to be in constant communication with them. Sometimes, we go see Legal because we want them to look at our documents. More senior roles are more involved with brand teams, clinical research, marketing and market access, to make sure regulatory requirements are aligned.

Question:	**Did you have a mentor? What is the most valuable advice he/she gave you?**
My mentor for regulatory affairs was my supervisor when I was doing my internship to obtain my M.Sc. He is associate director of regulatory affairs in a pharmaceutical company and he is also working for the program at Universite de Montreal. We would discuss the industry, how it was going and he was giving me advice when I was doing my interviews to obtain a job. He gave me lots of advice, but he said to keep going with what I was good at. Like attention to detail and put it forward. Since I was also thinking of doing project management classes, he confirmed that this kind of approach is really appropriate for an RA professional to develop.	
Question:	**What are the typical duties in a junior RA role?**
I can talk from my point of view, which is an RA associate for the Canadian affiliate of a global pharmaceutical company. RA encompasses many aspects so the duties will definitely differ based on where you work. It's really interesting to think that RA is bringing new medicines to the market, but most of our work is really to support keeping products on the market. As a junior associate, I did many product monograph updates. Being a global company, we have global labelling documents and they are updated regularly, annually or when needed. So these things have to be assessed at the local level and we have to file the submission with Health Canada and reply to their questions (Clarifax) in a timely manner, in collaboration with the subject matter experts from the company and negotiate the wording of the PM. I am also involved in assessing CMC changes to the products, for example to markings, formulation, site changes. It is very dynamic and I work with other team members to make decisions on how to capture and support these changes. Finally, depending on the company, a junior RAA might also be involved in filing Clinical Trial Applications (CTA), and subsequent amendments and notifications. As a junior, you can be also called in for helping with building New Drug Submissions (NDS) or Supplemental NDS (SNDS), for example for a new indication.	
Question:	**How do you keep skills current? What seminars or continuing education do you consider useful?**
Right now, I am in the learning phase so just by working as a junior RA associate, I learn new	

things every day. I also like to attend CAPRA dinner meetings, which are very interesting and close to our needs. I would also be interested in doing other classes from the DESS at Université de Montréal, for example on CMC subjects to better understand the vocabulary.