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:**
	DANNY GERMAIN
	DIRECTOR OF REGULATORY AFFAIRS (INNOVATIVE, GENERIC, OTC DRUGS)
	AVIR PHARMA / LABORATOIRE RIVA

Interviewer:	**Date of Interview:**
Janet Holden	21 February, 2020

The following questions and responses 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 you took to get to your current position?**

At the end of my BSc degree, I did an internship in a lab, and realized that I loved the healthcare field, but did not want to work in the lab. So, I looked at different programs in human biology and drug development. Regulatory affairs appealed to my broad interest in a variety of aspects of the drug development. I took the Master's program in drug development at the University of Montreal and then worked at a Contract Research Organization (CRO) in Regulatory Affairs for my U of M internship. I was offered a full-time job there after my internship. Afterwards, I worked at another company for 14 years before moving to my current position at AVIR.

Question:	**What is your educational background? Did you take a specific RA program? If so, what features of your RA program have been most useful in your job (e.g. internship)? If no, what aspects of your formal education did you find the most useful in your RA career?**

I did a BSc in Medical Biology, MSc in drug development, and a MBA. My MSc was in the drug development program at the U of M, which includes a specialty in Regulatory Affairs. This

program helped me the most to link together all the aspects of the pharma world in general.	
Question:	**What areas or features of the RA profession are the most interesting to you?**
I like the strategic aspects of the job, to achieve the best outcomes possible, and considering the different positions of commercial needs vs regulatory requirements. I also enjoy negotiating on behalf of my company with Health Canada to attain the best outcomes.	
Question:	**What are some of the useful traits/useful skills for your position?**
Strengths include organization, strategic planning, attention to detail, willingness to contribute, wanting to make a difference, and strong teamwork. I have been committed to make Regulatory Affairs a part of ongoing strategy development, and to make it more dynamic, rather than dry and boring. From my perspective, the most important trait is integrity in what we do, both with internal and external partners.	
Question:	**With which other departments or functional units within your company do you regularly interact with?**
Quality Assurance, Marketing, Sales, Medical Affairs, Pharmacovigilance, Supply Chain, Production and Legal Departments. I am working with more than 25 different clients/partners across the globe at a given time, so have to navigate different cultures, different work styles and lots of time zones!	
Question:	**Do you work individually or mainly in groups or teams?**
I mainly I work in teams.	
Question:	**Can you describe a regular work day in your position?**
No! There are no regular work days. I usually come to work with a list of things to do, but may only attend to a few of those items. There are always unexpected events such as project issues or questions from Health Canada that demand immediate attention. You have to be flexible and adaptable to changing priorities in this job.	

On a regular basis, planning for submissions and meetings, responding to the needs of different teams and due diligence are ongoing activities. As team leader, providing support and guidance to members of the department is also an ongoing activity.	
Question:	**If you could change any aspect of your job, what would it be?**
I would love to have unlimited resources! I would like to have more time to process information as it comes in before providing feedback or needing to take a decision, but things are moving at a high pace! There is not much I would change, I love what I do. I would not thrive in a position that is routine. I don't judge myself on the number of approvals I can get, but more on the impact of my work on the healthcare professionals and patients who need the medical products.	
Question:	**How do you keep your knowledge and skills current and up-to-date?**
I attend conferences, symposia, webinars and other educational events as time allows. I often go to CAPRA educational events. I find networking is also important to exchange ideas and share viewpoints. I like to understand the work of others to keep my knowledge current.	
Question:	**What advice would you give to students applying for internships and full-time RA positions?**
Don't underestimate the effect of a good fit into a team or organization. Don't limit yourself to finding work only at the larger, well-known companies. There are also lots of smaller companies who offer a great work environment where you can learn a lot, contribute greatly in a variety of areas and make a difference!	