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:
	SWAMY SUBRAMANIAN
	ASSOCIATE DIRECTOR, REGULATORY AFFAIRS
	APOTEX (GENERIC PHARMACEUTICALS)

Interviewer:	Date of Interview:
Janet Holden	23/01/2020

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?**

I did my graduate studies at UBC in pharmacology. At that time, I did not have a broad understanding of the RA field. Then, I read an article about the field of RA and thought it seemed like a very interesting career option. The field of RA gives you a more holistic view of the drug development from R & D through to the pharmacy shelf, rather than just focusing on a single area (such as R & D). I did some research and found the RA/QA Program at Seneca College in Toronto, so enrolled in the program and graduated.

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 my graduate studies in pharmacology. I studied at Seneca College (RA/QA Program) which also offers a field placement opportunity. From there, I got my first job.

Question:	**What areas or features of the RA profession are the most interesting to you?**
As I mentioned, I really like the holistic aspect of the RA field which allows one to be involved in so many aspects of the drug development and business organization. I enjoy the ability to interact across a variety of functional areas in the organization (market access, manufacturing, R & D, commercial operations, etc), as well as interacting with the regulatory agencies. Another exciting opportunity I have enjoyed is a leadership role, to help other individuals to grow within the organization.	
Question:	**What are some of the useful traits/useful skills for your position?**
In this field, you need a broad-based skill set. Excellent Communications – written and verbal, negotiating skills (internally and with regulators) Good interpersonal skills are essential to succeed in any business. Ability to understand the business aspects of the company. RA is not just a matter of submitting documents to the regulatory authorities, but to be a part of the strategy and understanding the impact to the business. Because of that, RA gets involved much earlier in the life cycle of the drug development to help move it through the process.	
Question:	**With which other departments or functional units within your company do you regularly interact with?**
The groups I interact with most frequently are Sales and Marketing / Commercial Operations, Business Development, R & D, Analytical Development and Clinical (for bioequivalent studies to be conducted for new generic drugs).	
Question:	**Do you work individually or mainly in groups or teams?**
Some work is done on an individual basis, such as interactions with the regulatory authorities. A lot of the work is done in teams to develop plans and strategies. A good mix of both, really.	

Question:	Can you describe a regular work day in your position?
No two days are the same. What I may plan in my mind or have listed to do for the day gets changed once I arrive at work. Many different situations arise that require immediate attention! The ability to prioritize is very important. Most days, there are lots of meetings to attend (cross-functional teams, core team, strategy meetings), individual work to support teams to move projects forward, and management of the team I lead (performance reviews, recruitment, etc).	
Question:	**If you could change any aspect of your job, what would it be?**
It would be nice to change the uncertainty of the job, and have more structured days, but that is not realistic. Everything else is ok.	
Question:	**How do you keep your knowledge and skills current and up-to-date?**
I regularly review new guidances and policies, and make use of our on-line library to read journals to keep my knowledge current and to be aware of changes in the regulatory landscape. I attend webinars as well as some in-person CAPRA educational events occasionally.	
Question:	**What advice would you give to students applying for internships and full-time RA positions?**
Have an open mind – RA is one area that can be unstructured and uncertain, as the challenges arise daily. Be ready to use communication and interpersonal skills which can be applied to anything you may be asked to do. Aim to learn the regulatory requirements. Be familiar with the general regulatory landscape. You don't need to be an expert in any one area. Be prepared to learn.	