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:**	
	KHALED YAHIAOUI	
	SENIOR PUBLISHING SPECIALIST, REGULATORY AFFAIRS	
	MERCK CANADA (REGULATORY OPERATIONS – ECTD PUBLISHING)	
Interviewer:		**Date of Interview:**
Janet		27/01/2020

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 have a background in biochemistry, bioinformatics and IT. I came into the field of Regulatory Affairs as I was very interested in electronic submissions, due to my previous knowledge and skill set.	
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?**
My background is in biochemistry, bioinformatics and IT. I also completed the Graduation Diploma in Regulatory Affairs from the University of Montreal – Faculty of Pharmacy. I found learning the many concepts around drug development along with my IT background helped me to understand how e-submissions are built, how the software works and what are the regulatory agency requirements in this area.	

Question:	**What areas or features of the RA profession are the most interesting to you?**
Data management and processing are very interesting to me. I like understanding how the information and documentation about drug development is submitted to health authorities, the formatting and how information is processed/reviewed by the health authority. Another area of interest is how electronic submissions are maintained (lifecycle). In addition, e-submissions is a dynamic area and the recent initiatives from Health Canada including the Regulatory Enrolment Process and Structured Product Monograph are good examples. Indeed, the future of drug submissions processing and management is becoming more and more electronic.	
Question:	**What are some of the useful traits/useful skills for your position?**
There are two types of skills – hard skills and soft skills. The hard skills have to do with a person's educational background and technical skills. The regulatory field is very dynamic and always changing. This offers many new opportunities to look forward into the future. Soft skills have to do with leadership and approachability. The Regulatory Affairs department is the final step before all the information on the development of a drug is consolidated and submitted to the health authorities. RA works both with internal colleagues and external health authorities. As such, it is important to be approachable and to work collaboratively with others.	
Question:	**With which other departments or functional units within your company do you regularly interact with?**
The main partners in my job are the medical writers, Regulatory Affairs submission content managers and project managers. These are the groups that provide the relevant documentation to include in the e-submisison.	

Question:	**Do you work individually or mainly in groups or teams?**
For content gathering and review, work is done in groups made of many individuals. When it is time to compile an e-submission, it is mostly an individual task.	
Question:	**Can you describe a regular work day in your position?**
The job consists mainly of compiling and assembling regulatory submissions, original submissions or supplemental submissions, and responses to information requests from the regulatory agencies. Regulatory information management (lifecycle) according to guidance from a regulatory and electronic perspective and archival of documentation (uploading submissions to a safe repository for future reference) are other key areas of responsibility.	
Question:	**If you could change any aspect of your job, what would it be?**
Improving the quality of the documentation of the documents provided for e-submission would make the job easier. There are going to be fewer and fewer .pdf and MS Word documents, as the e-submissions are moving to metadata and structured content. This is the future of electronic submissions. Also, improved quality of performance of the regulatory software would be helpful. More user-friendly software would be very helpful on a daily basis.	
Question:	**How do you keep your knowledge and skills current and up-to-date?**
I am RAC certified in Canada which means I must maintain my certification with continuing education. I participate in eCTD trainings, and am a lecturer at U of M in eCTD. I organize study	

groups at Merck to help others to achieve their RAC certifications.
I also attend symposia (Canadian or international) as an attendee or speaker to keep in touch with new regulations pertaining to electronic submissions.

Question:	**What advice would you give to students applying for internships and full-time RA positions?**

Do your best at the beginning to explain your technical skills and how you can contribute to the company. It is also important to show who you are as a person. Give the best of yourself every day, learning, improving and developing yourself. Remember to always behave professionally and strive to improve both hard and soft skills in partnership with the company.