Association canadienne des professionnels en réglementation

Canadian Association of Professional Regulatory Affairs

STUDENT RELATIONS COMMITTEE INFORMATIONAL INTERVIEW

REGULATORY AFFAIRS PROFESSIONAL PROFILE OF	Interviewee:
	MS. BEVERLY POND
	ETHICS & REGULATORY AFFAIRS OFFICER
	ONTARIO CLINICAL ONCOLOGY GROUP (OCOG)

Student Author:	Date of Interview:
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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: What is your educational background? What features of this training have been the most useful in your RA career?

I completed a BSc in Psychology/Biology, a 1 year post-graduate program in Neuroscience and a post-graduate Clinical Research Diploma from Humber College, which was the inaugural class for the program. The Clinical Research Program from Humber gave me the fundamentals and foundation for my career in clinical research, though at the time, the program did not delve as heavily into the regulatory aspects as the current program does. My degree in science has helped tremendously with the medical aspect of my career.

Question: What is the role of an Ethics and Regulatory Affairs Officer in the OCOG?

The Ethics & Regulatory Affairs Officer (ERAO) is responsible for the completion and submission of regulatory applications, review and approval of all site-ICFs (Informed Consent Form) as well as facilitating the local REB/IRB (Research Ethics Board/Institutional Review Board) submissions with sites and the collection, tracking and maintenance of all regulatory, start-up and close out documents. In addition, the ERAO provides direction and guidance for ethical and regulatory matters related to the conduct of clinical trials involving human participants for OCOG sponsored studies. The ERAO is also responsible for the OCOG Safety Desk; reviewing SAEs (Serious Adverse Events) and writing narratives.

Question: Can you pick a day from last week and describe what your work day/schedule was like? What did you have planned for the day?

I began my day by starting to prepare a Clinical Trial Application (CTA) for submission to Health Canada. I switched gears for 2 scheduled study meetings (I report on the status of regulatory approvals and start up for new studies and activation of protocol amendments) and then got right back to the CTA. I spent the afternoon reviewing ICFs from clinical centres, which require approval prior to ethics submission.

My door is always open for consultations or to provide guidance. As a result, I was also busy with responding to site questions and providing guidance (usually to ethics-related questions) throughout the

day as well as answering many emails and phone calls.

Question: What are some of the desirable traits/useful skills to your position and in RA?

Multitasking, listening and comprehension skills and teamwork are highly valued in this field. In addition, being able to apply my RA knowledge to clinical settings, to facility research and visualizing "outside the box" has been immensely useful.

Question: To how many industry associations do you belong? How are they helpful?

I belong to 3 associations: Canadian Association of Professional Regulatory Affairs (CAPRA), The Society of Clinical Research Associates (SoCRA) and the Canadian Bioethics Society. These associations provide current educational sessions for continued learning and provide an arena to meet people in the same industry and allow for idea exchange and feedback.

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

I really enjoy the collaboration with investigators and study team members.

Question: If you could change an aspect of RA, what would it be?

Occasionally, there is a perception that some researchers/investigators have that RA is a burden or hindrance to clinical research. I would change that perception to one of a more collegial relationship between the research side and the regulatory side.

Question: What trends and/or growth prospects do you foresee in the field of RA in general?

With the increasing regulatory and ethical requirements, I can see an increase in RA specialists in both industry and academia. I also anticipate increasing issues pertaining to facilitating clinical trials while reducing overhead/costs while maintaining high regulatory standards.