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STUDENT RELATIONS COMMITTEE INFORMATIONAL INTERVIEW

REGULATORY AFFAIRS PROFESSIONAL PROFILE OF	**Interviewee:**
	MILAN PATEL
	REGULATORY AFFAIRS PROJECT OFFICER
	DEPARTMENT OF NATIONAL DEFENSE

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: ***Can you pick a day from last week (or this week depending on when the interview is taking place) and describe what your work day/schedule was like? What did you have planned for the day? What did you encounter that was unplanned?***

I have many ongoing projects, which include providing regulatory advice during drug development and compiling NDSs. Most of the products we work with treat chemical and biological warfare, so for those kinds of indications there is no baseline patient population in which we can do efficacy studies. Efficacy studies therefore, must be completed in animal models. Current regulations state that you need evidence of efficacy in humans in order to get a drug approved. Since we can't have that we can't get any NDSs submitted and approved without a Regulatory amendment.

As a project officer, I spend a lot of time gathering information. My primary role is making sure that submissions are compiled and that the data needed for the submission is available and meets Canadian requirements. All of the research and development that happens for these drugs occurs in collaboration with NATO military organizations and/or pharmaceutical or biotech industry partners. So you have all these different entities doing various different parts of drug development and they need to be managed as far as data gathering is concerned for a Canadian NDS. So that is pretty much what I do, for the NDSs.

I also advise during R&D from a regulatory perspective. Most of our work in R&D is at an early pre-clinical, toxicology stage right now. Many of these projects involve novel, cutting-edge technologies so even the ICH guidelines don't give you the answers. I use my judgment and my experience to tell the R&D team what they need to include as the end-point for their studies, and what animals and how many to use, for example. I have to use judgment and discretion.

The physician in charge of the Canadian Forces operations determines what products we need. He may, for example come to me and say "there is this poison – find out if an antidote is available and see if you can get it under the Special Access Program." I have to do market research, find out where the antidote is manufactured and whether there is enough safety, efficacy and quality evidence to get a Special Access Program authorization for the product.

Question: What are the three most useful skills to your position?

I think communication skills are key because I'm dealing with a lot of Canadian companies and many NATO countries. When working with them, it is important to clearly identify your needs and to follow-up with further clarification if necessary.

You must also be confident in your abilities, your knowledge and your skills to be able to advise your superiors. When they ask me a question involving international partners, I have to be confident that I'm giving them the right answer or at least the answer that I believe is right. If I'm not confident about something, I look it up.

Many times there is no right or wrong answer, so judgment would be the third important skill. Many types of guidance documents are not sufficient. You have to use your judgment to provide a correct answer that would lead to the approval of a product.

Question: If you could change one thing about your position, what would it be?

Because we are working with public funds, we have to be prudent with what we spend. As a result, purchases (goods or services) take a lot longer than they would in the private sector. If I had the opportunity to somehow expedite the process in a way that was still fair and transparent, I would.

Question: How is employee performance evaluated at your organization?

In our organization, in the first three years you work, there is a detailed form that the current supervisor fills out. After the first three years, there is a short form that your manager may use and it includes a short paragraph describing your accomplishments in the last year. The annual performance review doesn't mean anything as far as your salary is concerned. Your salary is set by the Treasury Board of Canada, which does not get involved in your performance reviews. The reviews are good for employee morale and for keeping them up-to-date on their training and professional development.

Question: What kind of changes do you foresee in your industry?

I've been on a working group with Health Canada that is amending the Food and Drug Regulations to allow for defence drugs to get approvals. The draft regulations were published in Canada Gazette I in March. The 75-day comment period is now over and we just reviewed the comments last week. This initiative is something that's going to be a big change for us. By the fall, hopefully, these regulations will be published in the Canada Gazette II and based on the those regulations, the submissions that I have on regulatory hold will hopefully get reviewed and given an approval, and the submissions that we have been working on for the past year can actually be submitted. This will allow for a regulatory mechanism to have approved drugs that we can provide to the Canadian Forces.

Question: What areas in the industry have strong growth prospects in the future?

I really believe genetic therapies are growing right now. More and more gene-based therapies are being developed and in the last two years there have been two approvals of gene-based technology out of the FDA. Also, there are companies in Canada that are developing DNA or RNA-based therapies for anti-virals, anti-cancer agents – these are very cutting edge. I can see a lot of gene-based therapies emerging in the future.

Question: What features of your education/formal training are most useful in your career?

I got my BSc in Biology and Chemistry from the University of Toronto (U of T) and I attended the Regulatory Affairs program at Humber College.

I use what I learned in the Regulatory Affairs program at Humber on a daily basis. The regulatory affairs course provided me with sufficient background to allow me to grow in the field on my own.

I think experience really is very important. My internship at Humber and then the first year out of Humber, I gained great experience, and I use that experience every day in my day-to-day duties.

Question: To how many industry and professional associations do you belong?

I belong to CAPRA and DIA or RAPS. I switch back and forth between DIA and RAPS because it's expensive. One year I'm with DIA, and the next year I'm with RAPS. The DIA actually gives you a lot of information in the drug development field, which is really useful in my role as an advisor in drug development. It helps me give good advice and I can tell my peers what's going on in the industry and how everybody else is developing their drugs. RAPS and CAPRA give you the end-stage regulatory advice on how to manage your NDS and how to deal with the FDA and Health Canada. These are all very good organizations and they do give you very different sets of skills.

Question: How often do you travel (if at all) for conferences, meeting, etc.?

I attend a conference once a year. For work-related meetings, I travel once every other month on average to labs within Canada, US or UK.

Question: How did you get into regulatory affairs? Can you describe the career path you took to get to your current position?

That's an easy answer for me. Out of U of T, I was working in a chemical lab and I really didn't want to be in a lab. I went into the career centre at the university and saw an advertisement for the Regulatory Affairs program at Humber. I looked it up to find out what it was all about and I got interested, so I decided to go there.

Question: What types of experience did you gain in your first job?

It was all generic drugs, so I got experience in all aspects of an ANDS. I worked on the product monograph, the labeling and on Module 2 - QOS. I helped to assemble Module 5. I also worked in the international group, which was all CMC-based. The company did a great job at mentoring their students. They made sure I got a wide variety of experience.

Question: What skills would you say are the most useful to attain in one's first RA position?

If you're talking technical skills, at Humber you've done a lot of theoretical exercises, but actually addressing a situation is a whole different story. Getting the opportunity to work with many different issues and their resolution would be a great experience. Learning how to solve those issues gives you the ability and the confidence to allow you to come up with solutions for situations you've never come across before.