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STUDENT RELATIONS COMMITTEE INFORMATIONAL INTERVIEW

REGULATORY AFFAIRS PROFESSIONAL PROFILE OF	Interviewee:	
	HELEN BUCKIE	
	ASSOCIATE DIRECTOR REGULATORY AFFAIRS (FOCUS ON ADVERTISING AND PROMOTION, LABELING AND DIN OWNERSHIP)	
	VERTEX PHARMACEUTICALS	
Interviewer:		Date of Interview:
Janet Holden		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?
	<p>My background is from the marketing agency side, specializing in advertising, public relations, continuing medical education (CME) and inside sales among other things. I have always been in healthcare communications in some form or other.</p> <p>I was working as an independent contractor in healthcare communications when I became involved with my current employer as a subject matter expert in Canadian advertising guidelines and requirements (PAAB and ASC) and Health Canada's guidances as they are vastly different from the U.S.</p> <p>I like to continuously learn (life-long learner) and enjoyed the people and work so much with Vertex, I joined the company. This is my first experience within a pharmaceutical company.</p>
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)?



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	<p>If no, what aspects of your formal education did you find the most useful in your RA career?</p>
<p>I studied business. At that time there were no formal programs in RA. We fell into the field of RA by accident and learning on the job. Truly - curiosity and an open mind made it possible.</p>	
<p>Question:</p>	<p>What areas or features of the RA profession are the most interesting to you?</p>
<p>I really enjoy working on cross-functional projects where members of a variety of different disciplines work together towards one goal be it product labelling, advertising/promotion materials, or simply external communications.</p> <p>Of course, there is always independent work to contribute to the whole which in itself can be quite satisfying. Right now, I am enjoying being a mentor to the less experienced staff. I don't tell people how to do something-- just what results are expected and together we explore possible pathways. It is personally satisfying to see them create their own identity and thumbprint within the company and in their own professional development. Selfishly the sharing benefits me as well and sometimes challenges the why in processes.</p>	
<p>Question:</p>	<p>What are some of the useful traits/useful skills for your position?</p>
<p>I think the most important skills are:</p> <ol style="list-style-type: none"> (1) Communication and Clarity – it is important to clearly communicate information out to your vastly difference audiences as well as understanding the information coming in. (2) Agendas – It is important to ensure people understand why they are there and what is expected from them. (3) Meeting obligations/deadlines and keeping promises. It is essential to meet deadlines and keep the promises you make! 	
<p>Question:</p>	<p>With which other departments or functional units within your company do you regularly interact with?</p>
<p>I work with many different departments on labelling, DIN activities and advertising/promotional work such as: Artwork/TechOps, Commercial, Labelling, Regulatory Operations, Medical</p>	



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Affairs, Legal, Market Access, Biostatistics, Clinical Development, RA-CMC, Strategy, Patient Safety, IP and, of course, my country manager.

Question: Do you work individually or mainly in groups or teams?

I do independent work to contribute as a subject matter expert to the projects I am involved with, however the projects are completed by cross-functional teams.

Question: Can you describe a regular work day in your position?

There are no regular work-days! Every day is like a box of chocolates! You never know what you're going to get.

Each day, I work on the priority for that day, and the priorities change frequently.

Question: If you could change any aspect of your job, what would it be?

I think ambiguity can be difficult to manage. We are trained to work in a guideline and regulation driven industry. It is helpful to have clarity on what is being requested of me, so I know how to appropriately meet those needs. I like to know the end goal before initiating something – it keeps me focused.

Question: How do you keep your knowledge and skills current and up-to-date?

Groups like CAPRA are hugely important which offers something for a mixture of all Regulatory disciplines. Educational events, blogs, current issues of CAPRA's NOC magazine are timely and they give me insight into trends and future changes. I encourage everyone to attend a live CAPRA meeting to meet their future colleagues! My own internal surveillance of evolving guidance documents and regulations are useful ways to stay current in the field.

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



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I always advise students to be honest about who they are and what they like to do. It is best not to be “pigeon-holed” into one area until they have had a chance to learn about other functions. Volunteering for a variety of cross-functional projects is a good way to learn hands on from the experts. It also grows your network of colleagues and relationships. I also remind them that it is a small world, and that their reputation will follow them from job to job. If you have noble intent, curiosity, honesty, and work hard, people will remember you for that throughout your career.