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Association **c**anadienne des **p**rofessionnels en **r**églementation

Canadian **A**ssociation of **P**rofessional **R**egulatory **A**ffairs

STUDENT RELATIONS COMMITTEE INFORMATIONAL INTERVIEW

REGULATORY AFFAIRS PROFESSIONAL PROFILE OF	**Interviewee:**
	HEATHER GRAHAM
	MANAGER, REGULATORY AFFAIRS
	SANOFI PASTEUR

Student Author:	**Date of Interview:**
Lisa Pinto	August 24 2010

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?***

A typical day for me involves preparing Regulatory Strategy Documents, planning and/or preparing submissions for domestic or international Health Authorities, as well as meeting with cross-functional groups to provide regulatory feedback regarding planned changes that impact Sanofi Pasteur's licenses. Some unplanned activities included handling inquiries from other internal groups or departments concerning details in a particular license or inquiries from Health Authorities.

Question: ***How did you get into Regulatory Affairs? Can you describe the career path you took to get to your current position?***

I began my Regulatory career path upon completion of my graduate degree in Molecular Biology. I was looking for a position at a biotech company that would allow me to use the skills I obtained from my graduate education, with a specific focus on scientific/medical writing. My first job was at a small biotech company as a Regulatory Affairs Associate. This position required strong writing skills and a background in biotechnology and molecular biology. I learned the regulatory aspects of the position on the job and gained more experience through various positions and promotions. As of today, I have been a Regulatory Affairs Manager at Sanofi Pasteur for 2 years and I am currently RAC certified.

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

In my current position, I travel infrequently, perhaps once a year. However, in some of my previous positions I had the opportunity to travel a few times a year for internal company meetings as well as agency meetings and conferences.

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

I find my graduate degree in Molecular Biology very useful, particularly in my current position where I deal with vaccines and immunology. Additionally, I find the critical reading and writing skills I obtained as a graduate student to be very useful and important. Writing peer-reviewed scientific and review articles was excellent preparation for Regulatory Affairs as submissions are critically reviewed in the screening process. Strong writing skills are also essential for communicating with coworkers and Health

Agencies.

Question: ***To how many industry and professional associations do you belong? How have they been helpful to you in your career?***

I am a member of the Canadian Association of Professional Regulatory Affair (CAPRA), Regulatory Affairs Professional Society (RAPS) and American Medical Writers Association (AMWA). Each association is useful in different ways: CAPRA provides the opportunity to learn about issues that are specific to the Canadian Regulatory environment and network with local regulatory contacts. RAPS has resources for US and International Regulatory Affairs. The AMWA is a good resource to keep writing skills updated and accurate.