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STUDENT RELATIONS COMMITTEE INFORMATIONAL INTERVIEW

REGULATORY AFFAIRS PROFESSIONAL PROFILE OF	**Interviewee:**
	DR. STEPHEN SHERMAN
	MANAGER, BUSINESS DEVELOPMENT AND REGULATORY POLICY
	SANOFI-AVENTIS

Student Author:	**Date of Interview:**
C. Song	August 9 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: What is your educational background? What features of this training are most useful to your RA career?

I have a Bachelor and Master of Science from Queens University, a PhD from Memorial University, and an MBA from Queens University. Having practical experience in medical research, clinical research and publishing papers, I understand the limitations of how data is collected and analyzed. A regulatory professional needs to appreciate these aspects of the data making up the submission. My MBA training plays an important role in my career as I understand how business decisions are made and use the language of business as it relates to scientific issues. For example, when I look at a Product Monograph, I can assess it through the eyes of a scientist, a marketer, and a regulator.

Question: What is the role of Business Development and Regulatory Policy Management at sanofi-aventis?

In Business Development, we look for growth opportunities. For example, we may be interested in another company's product, either for purchase or to enter into a distribution agreement for that product in Canada. This requires an assessment of the product's chances of being approved by Health Canada and the benefit this product would provide to the patient. I spend roughly 60% of my time focusing on business development.

In Regulatory Policy, I spend about 40% of my time ensuring our company is an active stakeholder in Health Canada policy. This is accomplished directly, for example, by providing comments to draft policies and guidance documents. This can also be accomplished indirectly, for example, by contributing to Rx&D initiatives.

Question: Can you pick a typical day from last week and describe it?

My days are rarely typical. In Business Development, I work with cross-functional teams (Legal, Marketing, Quality Control, Industrial Affairs, Supply Chain), but most heavily with Business Development, Medical and Legal. A lot of co-operation is required between departments to assess all aspects of a product. I don't travel for business very much. Sometimes, when evaluating a product, travelling to the site is necessary so the dossiers with restricted access (so as to protect intellectual

property) can be reviewed. Sometimes as well, I may travel to Ottawa to support our partner company in their regulatory meetings with Health Canada.

Question: What are desirable traits in your RA co-workers/employees (name some useful skills)?

Communication skills are very important, especially written communication skills. Many important communications will occur through writing and your documents have to speak for you. For example, when requesting a Priority Review for a regulatory dossier, one has limited space and time to persuasively convey an important message. This is very challenging. Verbal communication skills are also very important for an RA professional, as they will often be negotiating and explaining issues, both internally (to other departments) and externally (to Health Canada or other companies). RA jargon and scientific jargon may not be clearly understood by other members of cross-functional teams.

Strong team work and collaboration is important in an RA professional. This applies not only within Regulatory Affairs but also with other departments.

Strategic-thinking skill is also an important trait in RA professionals, especially during negotiations. RA professionals should also be both optimistic and patient. Most submission files do not move as smoothly and as quickly as desired, so it is important to remain focused and motivated when facing these challenges.

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

I belong to CAPRA, DIA and RAPS. The benefits are the training provided and the opportunities to interact with regulators and industry peers. This CAPRA interview itself is a nice example of how we can learn from each other, the organizers should be commended for this idea. Industry associations provide great opportunities to share best practices, learn how other companies function, and meet with Health Canada outside of submission related meetings. As well, sanofi-aventis is a member of Rx&D, which is important in helping brand pharmaceutical companies share a common voice with regulators.

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

All aspects of RA are interesting. The bottom line – getting therapies to patients in order to help them is the ultimate motivator.

Question: What features of the RA do you find challenging?

The lack of predictability could be a challenging aspect of RA. Health Canada is different from the EU which has many guidelines in place to help industry understand what data and information is expected in a regulatory dossier for different types of products. In Canada, often a face-to-face meeting will be needed to clarify certain data requirements; however, it offers an excellent opportunity to build the relationship with the health authority.

Question: What kind of trends and growth prospects do you foresee in the field? For large multi-national companies, do you see local roles shrinking due to centralization at global headquarters?

The area of pharmacovigilance of products is growing. In general, Health Canada requires more post-market requirements to be fulfilled, PSUR reviews are growing, and risk management plans are becoming more frequent for companies.

The Progressive Licensing Framework (PLF), which has been renamed Legislative and Regulatory Modernization (LRM) will probably also expand the scope of responsibilities for local regulatory in Canada. Risk Management Plans and postmarket studies, which may need to be conducted in Canada

will increase pharmacovigilance workload and scope at least, if not other areas of regulatory. Since part of the goal of LRM is for Health Canada to be involved throughout the product's life cycle, more post market regulatory activities may be expected.