

Association
canadienne des
professionnels en
réglementation

Canadian
Association of
Professional
Regulatory
Affairs

STUDENT RELATIONS COMMITTEE INFORMATIONAL INTERVIEW

| | |
|---|--|
| REGULATORY AFFAIRS PROFESSIONAL PROFILE OF | Interviewee: |
| | JANET HOLDEN |
| | CONSULTANT |
| | JLH Regulatory Services Inc. 939 North River Road Suite 302 Ottawa, ON K1K 3V2 613-421-2058 |
| Student Author: | Date of Interview: |
| Margarette Sison | July 07, 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?*

Well, I had planned meetings throughout the day, but one or more were cancelled or postponed, so I had to be flexible and adapt to those meeting changes. As another example, on another day last week, I was going to write SOPs, but then other requests and demands from clients came along, and as a consultant I had to field those requests and help my clients. To summarize: you have to be flexible - when the client wants something, you have to be responsive and meet the needs of the client first.

Question: *What are the 3 most useful skills to your position?*

One is flexibility, as we discussed earlier. Being organized helps a lot and being able to multitask is essential in this area of industry.

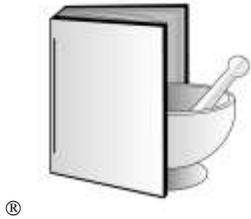
Question: *If you could change one thing about your position, what would it be?*

I don't know how realistic this is, but eliminating some uncertainty would be great. What I mean by that is that you can't plan what or when Health Canada will request information, or how they will review a submission, or even predict when a crisis of some sort is going to come about. It would be great to see the future.

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

In general, for the health care industry, I think there will be tighter budgets, more external oversight or governance. This external oversight or governance will have to do more around compliance issues. For example, there will be tighter budgets and stricter governance over medical representatives, and how representatives promote their products to doctors. I also think that the big healthcare reform will come into play in the US and the world is going to feel that too.

As far as our industry goes, I think there will be an increased shift to emerging markets, like China and



Association
canadienne des
professionnels en
réglementation

Canadian
Association of
Professional
Regulatory
Affairs

India, for clinical trials, as well as for manufacturing.

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

As I said earlier, I think that the emerging markets will play an important role in the future.

New technologies will definitely drive the growth in the future as well. Personalized medicine will allow medicines to be tailored to patients' needs based on their genetic profile. Anything to do with genetics will be an interesting area to watch; there will be more diagnostic capabilities, gene therapies, etc.

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

I think my scientific background has helped me a lot. I have a degree in microbiology and it has helped me understand the terms and processes. A scientific degree will definitely facilitate product knowledge and I think it's important to have some knowledge of different areas in science. As you know, this field encompasses more than just one area, so having that breadth of scientific knowledge is important.

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

I sit on CAPRA's board of directors, and am also a member of RAPS and PSG (Pharmaceutical Sciences Group).

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

For conferences and meetings, I'd say about 3 or 4 times a year. Business meetings that require travel are taken as needed. I also sit on the board of directors for CAPRA, so I have to travel a few times a year for that, but only because I'm based in Ottawa.

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

laughs

Well, we're going back 23 years now, but I guess you can say that I've never really had a predetermined career path. Curiosity and hard work brought me into Regulatory Affairs. I began my career in sterility testing for a large vaccine manufacturer. If you want to learn good aseptic technique, work with vaccines! My desire to learn and grow drove me to try different jobs within the industry, and more hard work and curiosity drove me to more opportunities. I took on a variety of roles in Quality Control and Quality Assurance, like validation and auditing, but it was only after 4 years in industry that I shifted to RA.

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

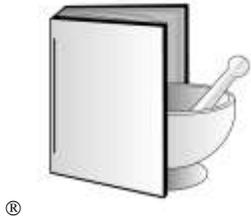
My first regulatory job was preparing submissions for bacterial vaccines.

I gained a lot of experience in international regulations for the Europe and South and East Asian markets, as well as improved my knowledge of geography.

I also learned and experienced the way different people and different cultures operate.

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

Attention to detail is key. A willingness to learn is also important. You definitely need to have skills in gathering information from a variety of sources, and must be able to work within a team. You need good communication and presentation skills, a solid understanding of regulations. Providing good customer service is also an important component. What a lot of people don't realize when they're starting out is that your employers and your colleagues are your customers and your work is a service to your



Association
canadienne des
professionnels en
réglementation

Canadian
Association of
Professional
Regulatory
Affairs

customers. It's simple: smile and be nice to people, and do what you say you're going to do. Meeting deadlines is also crucial.