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STUDENT RELATIONS COMMITTEE INFORMATIONAL INTERVIEW

REGULATORY AFFAIRS PROFESSIONAL PROFILE OF	Interviewee:
	MS. AIDEEN KENNEDY
	MANAGER, REGULATORY AFFAIRS
	CANADA MICROSURGICAL LTD.
Student Author:	Date of Interview:
Nancy Ling	June 23, 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: How did you develop your Regulatory Affairs career to get to your current position?

I have a Master's degree in Toxicology from University of Ireland. At the time, there were new Directives in European Union, so I was offered the opportunity to work in International Regulatory Affairs.

Question: What were your biggest challenges as a RA professional and how did you overcome them?

In most organizations, the role of Regulatory Affairs is not understood.

The biggest challenge I encountered in my previous three organizations is overcoming the negative perception associated with the Regulatory Affairs role. I had to overcome this negative perception by actively participating in non RA core team activities and learn to talk the language of important internal customers.

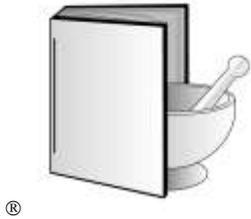
Another challenge is that RA process is perceived in an organization as cost versus revenue generating. I overcame this challenge by describing how having a RA department is a competitive advantage over our competitors. It provides a signal to Health Canada that our organization is serious about safety and effectiveness. A dedicated RA professional can establish relationship with HC which translates to trust. In my experience this results in Health Canada not asking for extra information, shortening review times, allowing fee reduction, etc. It contributes to the bottom line by reducing costs and timelines and establishes reliable revenue generation.

Therefore, as a RA professional, we need to be self motivated and learn all important aspects of the business, step out of our comfort zone and sell ourselves. We can often offer potential solutions by following the RA process..

Above all, we should always use positive words, not "cannot do."

Question: What specific industries do you see strong growth potential in the future? Can you be also specific regarding the RA role(s)?

Companies in biologics, molecular diagnostics, combined medical devices/pharmaceutical, etc., will be the strong performers of the future.



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Question: What is the most enjoyable aspect of your role at Canada Microsurgical Ltd?

I enjoy creating files for submission. I have learnt through experience what information is important for each country. When I read through EU and US submissions, I can extract key points for Canadian submissions efficiently. Additionally, you are exposed to complaints, customer visibility, sales material, R&D material, and clinical information. So you are basically the most knowledgeable person regarding the company's product(s)!

Question: When recruiting staff for your department, what attributes or work experience do you consider crucial?

For entry-level position: sound background in GMP and regulatory affairs basics; ability to understand corporate culture-ultimately an indication of leadership skills; methodical thinking; process oriented thinking; detail oriented; product knowledge; and strong understanding of customer's view.

Question: Where do you see yourself in the next 3-5 years?

I have worked for Boston Scientific, Becton Dickinson, CanReg before joining Canada Microsurgical. Throughout my career, I have gained Regulatory Affairs experience in veterinary products, medical devices, IVDDs, NHPs, and pharmaceuticals. I have also worked as a consultant. At Canada Microsurgical, I started a RA department and will gain experience with ortho products. In the future, I would like to continue applying the RA process/thinking into other areas such as molecular diagnostics or international RA.