

®



Canadian  
Association of  
Professionals  
in Regulatory  
Affairs

Association  
canadienne des  
professionnels en  
réglementation

## Canadian Association of Professionals in Regulatory Affairs/Association canadienne des professionnels en réglementation

### STUDENT RELATIONS COMMITTEE INFORMATIONAL INTERVIEW

<b>REGULATORY AFFAIRS PROFESSIONAL PROFILE  OF</b>	<b>Interviewee:</b>
	<b>AMÉLIE LACROIX</b>
	<b>LEAD, REGULATORY BUSINESS PROCESS</b>
	<b>PHARMASCIENCE</b>
<b>Student Author:</b> Ginny Kwan	<b>Date of Interview:</b> April 04, 2014

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:

<b>Question:</b>	<b>Can you describe your job and explain how it relates to regulatory affairs?</b>
	<p>As Lead, Regulatory Business Process, I manage process improvement projects within the Global Regulatory Affairs department. In addition, I am also responsible for our overall project portfolio in making sure that the projects are aligned and that they work in synergy towards achieving Global Regulatory Affairs' strategic objectives.</p> <p>The process improvement projects aim at increasing our level of regulatory competitiveness by targeting various objectives such as expertise, communication &amp; collaboration, operational effectiveness and efficiency, knowledge management and strategic initiative. Projects include automation of business processes, implementation of new work methodologies, launch of new information and knowledge management systems, etc.</p>
<b>Question:</b>	<b>What are some of the desirable traits/useful skills for your position and in RA?</b>

A strong knowledge of project management principles and best practices is definitely a must for this type of position, as well as knowledge of process improvement methodologies such as Six Sigma. Experience in regulatory affairs is also a definite plus because it allows to understand the business needs and to design projects that can respond to those needs. Above all, you need to be able to work in teams, to be transparent and to be willing to challenge yourself and others.

**Question:** With which other departments or functional units within your company do you regularly interact with?

All regulatory affairs teams (Canada, Innovative, and International), regulatory operations, business units, project management, quality assurance, etc... Basically, we interact with all internal clients and supporters of Global Regulatory Affairs. As many of our projects have an IT component, we also work hand in hand with that department.

**Question:** What percentage of your time is spent doing what?

I would say that 90% of my work has to do with communications – with the project teams, stakeholders, etc. Process improvement projects require constant monitoring in order to make sure that they stay on time and on scope, that they respond to the needs of our internal clients, and that they are in line with our departmental objectives.

**Question:** How are work teams or groups organized?

We are two project managers in my team and we each have our own projects. We work very closely together to make sure that our projects and strategies are aligned. Our project teams mainly involve people from various regulatory affairs teams & regulatory operations (functional experts) and IT (in charge of any IT portion of projects).

**Question:** What is the most enjoyable aspect of your role at your company?

I love that I am in a position to really make a difference for my department. Every day, I see our projects moving forward and how this is helping us to grow both as a team, but also as a player in the industry. I have the chance to work with amazing people from all over the organization and this brings me a lot both on the professional and personal sides.