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STUDENT RELATIONS COMMITTEE INFORMATIONAL INTERVIEW

REGULATORY AFFAIRS PROFESSIONAL PROFILE OF	Interviewee:	
	EMMA CASS	
	SENIOR SPECIALIST - PHARMACOVIGILANCE	
	EMERGENT BIOSOLUTIONS (INNOVATIVE PHARMACEUTICALS AND BIOTECH)	
Interviewer:		Date of Interview:
Janet Holden		24/01/2020

The following questions and responses 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 get into Regulatory Affairs? Can you describe the career path you took to get to your current position?
	I got into this field of work accidentally. I was working in the area of chemical engineering and then transitioned into Clinical Research which led me into Pharmacovigilance. I was working with a Contract Research Organization and pharmaceutical services provider for clinical research and PV respectively with marketed products when I became involved in pharmacovigilance, which I enjoyed and therefore expanded into PV full time. That is what got me interested in my current career.
Question:	What is your educational background? Did you take a specific RA program? If so, what features of your RA program have been most useful in your job (e.g. internship)? If no, what aspects of your formal education did you find the most useful in your RA career?
	I studied chemistry, biochemistry, and chemical engineering formally. I did not take a formal course or RA degree, but rather a variety of courses in pharmacovigilance and clinical



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research along the way. My educational background allowed me to have a very thorough knowledge of chemistry and biochemistry to understand how drugs work on the body. Analytical thinking is also another key skill that I acquired.

Question: What areas or features of the RA profession are the most interesting to you?

I am mostly interested in my current role in Pharmacovigilance. Patient safety and ensuring that products are safe and effective is very important to me.

Question: What are some of the useful traits/useful skills for your position?

I have been called stubborn, which I consider to be a compliment. In my job, I have to be persistent and determined to get the information I need about a patient safety event. Attention to detail is also crucial as is flexibility, so as to understand the global legal requirements and why they exist.

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

On a regular basis, I interact with the Quality Assurance, Medical Affairs, Clinical Research and Development, Sales and Business Development and Legal departments.

Question: Do you work individually or mainly in groups or teams?

Both. We are a fairly large team. We all work independently (e.g. product experts) but also review each other's work for content and accuracy.



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Question:	Can you describe a regular work-day in your position?
<p>There is no regular work-day! Things change daily. Each day is dependent on the number and types of patient cases that come in that have to be reviewed, investigated and reported to regulatory agencies within specified timeframes.</p> <p>In addition to safety reporting of patient events, we also have to consider patient privacy legislation and negotiating privacy agreements with end users (e.g. purchasers/pharmacies in different countries).</p>	
Question:	If you could change any aspect of your job, what would it be?
<p>The job is what it needs to be to get the job done properly. Better access to medical information would be helpful but we have to consider patient confidentiality and their right to say no.</p>	
Question:	How do you keep your knowledge and skills current and up-to-date?
<p>We are constantly reviewing current and local laws in our job. Relevant webinars and conferences also help to keep our knowledge current.</p>	
Question:	What advice would you give to students applying for internships and full-time RA positions?
<p>You need to have patience and be prepared to learn new things every day. This is an environment of continuous learning.</p>	