Professional Development

In our Next issue
Regulatory Intelligence and Transparency
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## FOR CONTRIBUTED ARTICLES

**ARTICLES** should be sent to Editor@capra.ca. Please submit a synopsis of the article or a general idea prior to the final article in order to avoid duplication of ideas. All contributions are reviewed by the Editorial Committee for quality of content, style, length, grammar and punctuation. NOC does not guarantee publication of the submitted articles. Articles can be based on important regulatory developments or on the central theme for our next issue: professional development.

**LENGTH OF ARTICLES:**
Feature articles based on issue themes: **1500-2500 words**.
Letters to the Editor: **300 words maximum**.

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ONLINE REGULATORY AFFAIRS TRAINING FROM THE US:
An Alternative for Canadian Regulatory Affairs Professionals

Online learning has redefined our idea of a “classroom” and has allowed us to break through geographical boundaries to pursue education offered from around the world. In the last decade, a variety of regulatory affairs training programs have been created based on an online model, giving Canadian regulatory affairs professionals an alternative to physical classroom training.

One of the key advantages of online learning is the convenience of “attending” classes. Physical classrooms have been replaced with virtual ones which save on time spent traveling to campus. Connection to the virtual classroom can be performed from the comfort of your own home or even your office on those evenings when you are rushing a submission deadline. A simple click of the mouse can provide access to course materials, online textbooks, discussion posts and assistance from instructors. If your class features a live webinar at a time inconvenient for you, you can safely log in later, as the live sessions would have been recorded for students who were unable to attend the meeting. With online learning, one will be hard-pressed to find an excuse for “missing” a class. Evidently, it is the promise of convenience which has enticed many working professionals to consider online learning.

Although most of the online regulatory affairs training programs are offered from educational institutions located in the United States, students can enrol from anywhere in the world. What this means is that a Canadian student can collaborate on a class project with students from Asia, Europe or Latin America. This opportunity to interact and collaborate on projects at the international level can be an enriching experience for aspiring regulatory affairs professionals, particularly those who intend to work on regulatory activities and projects at the international level. Learning to navigate the regulatory and cultural differences of other countries is an important and challenging aspect when working in regulatory affairs at the global level. The only caveat to take into consideration is the different time zones which must be considered when planning virtual group meetings. This means you may have to attend meetings very early in the morning or late at night in order to accommodate your teammates from other continents.

There is a general misconception that online learning consists of simply reading course notes uploaded by the professor and completing electronic quizzes, usually believed to be in the form a multiple choice format. This is not completely true. In the most basic model of online learning, yes, it can be that simple. However, most online courses today are much more interactive and engaging, and are based on sophisticated IT systems and tools. Online lessons can be presented as narrated slideshow presentations, recorded audio lectures, live webinars or webcam sessions. Class discussions between classmates can also occur on discussion platforms, live chats or teleconferences. In addition, assigned group projects force students to learn how to interact and work strictly via correspondence, an important skill set in today’s work environments more collaborative projects are done entirely via correspondence. Ultimately, the format of the online course is left to the professor’s teaching preference.

Although one does not necessarily have to be tech savvy to take online courses, students must be able to comfortably navigate through IT platforms such as Blackboard, Moodle and SharePoint in order to access course materials, share documents, participate in discussion boards and submit assignments and coursework. The ability to work with electronic document sharing systems is an attractive skill to possess as more and more documents are presented in electronic format and submissions are being delivered electronically. This transferable skill is another important asset acquired through online learning.

Finally, it should be mentioned that online learning requires a certain level of discipline and self-motivation. Without a fixed class schedule, it can be very easy to fall behind. Therefore, it is strongly recommended that students strictly adhere to the agenda designed by the professors in order to avoid last minute cram sessions before an assignment or a test. Nose to the grindstone.

Let us explore some of the online regulatory affairs training programs currently being offered from American institutions.

Universities

JOHNS HOPKINS UNIVERSITY

Johns Hopkins University (Rockville, MD) offers an online Master of Science (MS) in Regulatory Science program, formerly the MS in Bioscience Regulatory Affairs, through its Krieger School of Arts and Science. Designed for working professionals, the objective of the program is to provide students with a specialized course of study emphasizing advanced topics in the regulatory approval processes for global and domestic biotech products. The program is comprised of 10 courses, including 6 core courses related to regulatory affairs, GMP and clinical development of new drugs and biologics and 4 elective courses depending
on the student’s particular areas of interest. Some elective courses include Validation in Biotechnology, Managing Innovation in the Life Sciences, Medical Device Regulation and Regulatory Strategies in Biopharmaceuticals. The program can typically be completed in two years, on a part-time basis.

Jamie Austin, a graduate of the program, works as the Coordinator and Academic Advisor for the Regulatory Science Program at Johns Hopkins and has gone on to do a great deal of consulting work in the Canadian market. Ms. Austin explains that although the details and organization of the American and Canadian regulatory framework are different, the underlying skillset necessary to succeed as a regulatory professional remains the same. She says, “Think of it this way: Our courses are designed to teach regulatory science. The science really doesn’t change.” While the emphasis of the program is regulatory affairs for the US Foods and Drugs Administration, Ms. Austin maintains that the courses are based on regulatory principles and approaches valuable for regulatory professionals in any market. For Canadian students, Ms. Austin recommends pursuing the International Regulatory Affairs course or to consider focusing on a particular area of Canadian regulatory affairs in a supervised, Independent Study project.

Interesting Facts: Many of the professors in the program also work for the FDA. In addition to online courses, the program also offers physical classes at its Montgomery Campus in Rockville, MD.

NORTHEASTERN UNIVERSITY
Northeastern University (Boston, MA) offers an online program in Master of Science in Regulatory Affairs for Drugs, Biologics, and Medical Devices. The program is designed to deepen the understanding of current regulations and their practical application in the development and commercialization of drugs, biologics, and medical device products. The program is comprised of 10 courses, including 6 core courses based on new drug, medical and biologics development and 4 electives courses. One elective course must be selected from each of the following 4 disciplines: Safety and Surveillance, Business and Law, Development and Strategy and International.

Robert Yu, a Canadian Regulatory Affairs Associate at Pharmscience in Montreal, is a graduate of the program. Mr. Yu feels that it is important to have an understanding of FDA regulations as they are in line with International Harmonisation (ICH) guidelines. He recommends that students entering into the program should have a basic knowledge of regulatory affairs to truly grasp the topics discussed in the courses. Mr. Yu says although the program focused on American regulations, his training from Northeastern University has helped him understand the regulatory strategies when dealing with Canadian regulations. He also adds that Canadian students can choose courses such as Canadian and Australian Medical Device Regulations and Global Awareness: Canada, Asian, and Latin American Regulatory Affairs, which are relevant to other international regulatory systems.

In addition to the Master of Science program, Northeastern University also offers a shorter Graduate Certificate in Biopharmaceutical Domestic Regulatory Affairs. The Graduate Certificate is based on 3 core courses related to new drugs, medical devices and biologics development as well as one elective course based on the student’s regulatory interests. Courses from this Graduate Certificate can be applied towards the Master of Science program. Therefore, a student who has initially decided to pursue the Graduate Certificate can switch to the Master in Science program by carrying over the completed credits.

In addition to online courses, the program also offers physical classes at its main campus in Boston as well as in Charlotte, NC and Seattle, WA.

Professional Associations
REGULATORY AFFAIRS PROFESSIONALS SOCIETY (RAPS)
The Regulatory Affairs Professionals Society (RAPS) also offers an online Regulatory Affairs Certificate Program. The program is available in three options: medical devices, pharmaceuticals and dual in medical devices and pharmaceuticals. The curriculum for the certificate will vary depending on the chosen option and is highly customizable with 4 core courses and 5 elective courses. The core courses are based on topics such as Ethics, Global Regulatory Strategy and the role of the Regulatory Affairs unit within a life sciences company. The structure of each course is typically comprised of interactive exercises, detailed explanatory text, engaging graphics, and hyperlinks to additional reference material and resources. A short quiz at the end of each lesson is designed to evaluate the student’s understanding of the topics and an all-inclusive final exam measures the student’s overall comprehension of the course’s subject. The duration of the certificate program is six months.

The Regulatory Affairs Certificate Program must not to be confused with the RAPS Regulatory Affairs Certification (RAC). The Regulatory Affairs Certificate Program is a series of online courses designed to give a focused understanding of specific healthcare products including pharmaceutical products and medical devices and does not have any renewal requirements. The RAC, on the other hand, is a credential or a professional certification earned by passing a formal exam.

The RAPS lessons are completed at the student’s pace, provided that they are completed within a six month time frame. An online sample lesson is available on the RAPS website: http://www.raps.org/Portals/0/multimedia/onlineu-demos/story.html

As the demand for online regulatory affairs training increases and technological advances continue to refine the way online lessons are presented, the format of online regulatory affairs training will continue to evolve as new programs are created. Professionals who wish to enhance their professional development with regulatory affairs training should consider programs which can help prepare them for regulatory affairs projects at the international level.

Ginny Kwan is a Publisher in the Regulatory Operations team at Pharmscience, Montreal, specializing in electronic submissions and the life cycle management of electronic submissions. Ginny has a background in computer system validation, with a focus on electronic document management systems and digital signatures. She is also currently completing her Master of Science in Regulatory Science at Johns Hopkins University. She is an active member of the CAPRA Student Relations Committee and regularly attends CAPRA dinner meetings held in Montreal.