Seneca POLYTECHNIC

PHARMACEUTICAL REGULATORY AFFAIRS & QUALITY OPERATIONS (RAQC)

About the Program

Focus your career by specializing in this one-year graduate certificate program. You will gain a fundamental understanding of regulatory affairs and quality operations. Studies of regulatory compliance in Canada and internationally will prepare you for a career involving drug or medical regulations and quality assurance functions and roles. During the first semester, you will learn the fundamentals of regulatory affairs and quality operations. Your second semester will focus on more detailed exposure to the areas of regulation and quality operations. This program offers an optional work term(s), similar to the length to an academic semester, if you meet all the academic requirements.

Part-time option is available > (http://www.senecapolytechnic.ca/ce/ community/health-care/pharma-reg-affairs-quality-operations-grad-certificate.html)

Credential Awarded

Ontario College Graduate Certificate

Duration

2 Semesters (1 Year)

Starts

January, May, September

Program and Course Delivery

This program is offered online and is also available in Seneca's flexible delivery format. With flexible delivery, using innovative learning spaces and technology, professors teach students in a classroom or lab and broadcast in real time to students attending remotely. In flexible courses, students have the choice of coming on campus or learning online.

Skills

Throughout this program you will develop the following skills:

- Understand Canadian and international drug and other health care legislation, regulations and guidelines
- Understand process, regulations and the impact of manufacturing
- Prepare submissions, including supplemental documentation, to the Therapeutic Product Program
- Understand good manufacturing processes
- Negotiating in managing the review process

Work Experience
Optional Work Term

Students meeting all academic requirements may have the opportunity to complete an optional work term(s) in a formal work environment. The work term(s) is similar in length to an academic semester and typically involves full-time work hours that may be paid or unpaid. In programs with limited work term opportunities, additional academic requirements and a passing grade on a communication assessment may be required for eligibility. Eligibility for participation does not guarantee a work position will be secured. Additional fees are required for those participating in the optional work term stream regardless of success in securing a work position.

Review eligibility requirements for work-integrated learning (https://www.senecapolytechnic.ca/employers/seneca-works/work-integrated-learning/eligibility.html)

Your Career

When you graduate from this program, these are the types of career options you can explore:

- Regulatory affairs associate
- Regulatory affairs assistant
- Quality assurance associate
- Quality assurance investigator
- Documentation administrator
- Medical information associate

Affiliations/Associations

- Canadian Association of Professional Regulatory Affairs (CAPRA)
- Drug Information Association (DIA)
- Pharmaceutical Sciences Group (PSG)
- Regulatory Affairs Professional Society (RAPS)

Program of Study

Course Code	Course Name	Weekly Hours
Semester 1		
PBB814	Biotechnology and Biopharmaceuticals	4
PFM714	Product Formulation and Manufacturing	3
PQA711	Introduction to Quality Assurance	3
PRA700	Introduction to Pharmaceutical Regulatory Affairs	6
TWC713	Technical Writing and Communication I	3
WTP100	Work Term Preparation [*]	1
Work-Integrated Learning Term		
RAQ441	Pharmaceutical Regulatory Affairs, Work Term [*]	30
Semester 2		
IRA815	International Regulatory Affairs and Harmonization	3
PCR901	Introduction to Clinical Research	3
PEC715	Pharmacoeconomics	3
PQA811	Quality Assurance II	4
PRA800	Regulatory Affairs II	6

* Work-Integrated Learning option only

Program Learning Outcomes

This Seneca program has been validated by the Credential Validation Service as an Ontario College Credential as required by the Ministry of Colleges and Universities.

As a graduate, you will be prepared to reliably demonstrate the ability to:

- Describe the government process within the Canadian health care system and provincial formularies.
- Explain the roles and responsibilities of a regulatory professional in industry.
- Explain the concepts in pharmacoeconomics as they relate to the socioeconomic aspects of health care and health care products.
- Explain Canadian and international health care legislation and regulations.
- Describe international harmonization of regulations and the impact on manufacturing and the submission process.
- Demonstrate information technology skills in the use of software applicable to regulatory affairs submissions, in document and database management systems, and in the use of the Internet for research.
- Explain the Product Development Process.
- Outline the Quality Control Process.
- Define drug, medical device, and biologic submission process requirements.
- Prepare a drug, medical device, and biological submission to the Therapeutic Products Program (TPP) including supplemental documentation.
- Demonstrate the problem solving process as it relates to post-marketing surveillance and pharmacovigilance.
- Demonstrate effective interviewing and negotiating skills in managing the review process.

Admission Requirements

- Ontario university or college degree or equivalent in science with a focus on chemistry, biology or pharmaceutical
- English proficiency (https://www.senecapolytechnic.ca/registrar/canadian-applicants/admission-requirements/english-proficiency.html) for graduate certificates

Canadian citizens or permanent residents educated outside of Canada must provide a World Education Services (WES) or ICAS Canada credential evaluation.

Pathways

As a leader in academic pathways, we offer a range of options that will allow you to take your credential further in another Seneca program or a program at a partner institution.

To learn more about your eligibility, visit the Academic Pathways (https://www.senecapolytechnic.ca/pathways.html) web page.

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